Technical Implementation Plan:
Core Health Information Exchange (HIE) Services

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Preface

The following document is Cal eConnect's Technical Implementation Plan developed with assistance from the California eHealth Collaborative (CAeHC) in June of 2010. The Technical Implementation Plan is intended to provide the steps necessary to operationalize California's HIE Strategic and Operational Plan. The Technical Implementation Plan reflects the agreed-upon framework described in the HIE Strategic and Operational Plan for creating the core services deemed essential to establish the trusted infrastructure for HIE at the state level. The plan acknowledges the fluctuating and evolving nature of industry standards and federal requirements related to sustaining statewide HIE.

Cal eConnect is posting this document along with an addendum to the plan that includes proposed Technical Specifications for the Core Services. Cal eConnect has made significant strides in various aspects of the plan and is looking forward to engaging a qualified vendor to stand-up and support the Core Services, which will serve as the foundation of the trust relationship required to enable the private and secure exchange of electronic health information.

Thank you for your interest and input. To submit comments, please visit www.caleconnect.org for the RFIPC submission guidance. The deadline for responses is September 30, 2010.

Cal eConnect, Inc.
September 9, 2010

Cal eConnect, Inc.

Technical Implementation Plan

Working Draft

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I. Executive Summary

Introduction[1]

Cal eConnect, Inc. is a private, nonprofit corporation established by the stakeholders of California and designated by the State of California to provide leadership and oversee a collaborative process for developing and supporting health information exchange (HIE) policies and services in California. Cal eConnect is tasked with establishing ground rules by which health information can be exchanged appropriately among clinicians, hospitals, health plans, patients, and government programs, including public health and Medi-Cal. It also oversees and manages implementation of HIE services throughout the state under a federal grant California received as part of the American Recovery and Reinvestment Act (ARRA), known as the HIE Cooperative Agreement Program.

The Cal eConnect Technical Implementation Plan ("Implementation Plan" or "the Plan") is intended to guide the implementation of California's HIE Strategic and Operational Plan[2], a collaborative product of hundreds of stakeholders across the State, which was submitted by the California Health and Human Services Agency (CHHS) to the Office of the National Coordinator (ONC) in April. The Implementation Plan identifies tasks to be accomplished in the first 18 months of implementation (from July 2010 to December 2011). The Implementation Plan is organized according to ONC's "Five Essential Domains of HIE": technical architecture, governance, business and technical operations, legal and policy, and finance.

Background and Approach

The immediate goal of Cal eConnect is to enable providers in California to achieve the "meaningful use" of Electronic Health Records (EHR) by exchanging information electronically as defined in the Centers for Medicare and Medicaid Services' (CMS) December Notice of Proposed Rulemaking (NPRM).

Because of the large number of stakeholders and the diverse geography of California, Cal eConnect is taking a market-based approach to define its strategy for enabling meaningful use by dividing the State into three target market scenarios. The scenarios include: Rural Communities, Urban Health Information Exchange and Unaffiliated Providers. Cal eConnect is gathering market data for each scenario to highlight the opportunities to be either a direct provider of core technical and policy solutions or a contract partner to the stakeholders for the development of services.

Requirements driven by the Meaningful Use NPRM and the Nationwide Health Information Network (NHIN) standards, among other inputs, suggest that a "trust architecture" is needed as the first step to enable exchange in the State. Therefore, this implementation plan focuses on steps to build and operate that trusted foundation of services, while other value-added services Cal eConnect should offer will be determined as the strategy work above is completed.

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[1] Note that definitions for key terms in this document can be found in Appendix 1.

[2] California used broad stakeholder input to develop Strategic and Operational Plans for the State Health Information Exchange (HIE) in accordance with the guidance outlined in ONC's Cooperative Agreement for State HIE. The two plans have been merged into one document and resubmitted to ONC as the CA HIE Strategic and Operational Plan: http://www.ehealth.ca.gov/eHealthPlan/tabid/72/Default.aspx.

Technology Architecture

Cal eConnect will first develop a set of Core Services, or a "trust architecture", that is necessary to enable the meaningful use of EHRs relevant to information exchange. These HIE-relevant meaningful use criteria can be found in Table 2. Cal eConnect will also consider offering value-added services that would further enable meaningful use, the first of which is a Lab Service.

Core Services

The key software components that make up the statewide infrastructure are comprised of an Entity Registry and a Service Registry and are based on specifications and standards developed through a Messaging and Authorization Framework.

- **Entity Registry:** The Entity Registry provides a trusted registry of Entities engaged in HIE transactions and the systems that may be the senders or recipients of health information. The registry comprises part of a federated identity management system for HIE, and serves to inform parties and systems engaged in HIE transactions about the validity and authenticity of exchange partners.
- **Service Registry:** The Service Registry provides information about where to direct transactions intended for specific individuals or systems, such as providers or their specific EHRs, and how to formulate the transactions so that they can be correctly processed when received.

The Entity Registry would be the first service offered by Cal eConnect, as it is commercially available and necessary at the state level to provide HIE transactions across California. The estimated cost of implementation is less than $1M and is a requirement in every scenario. From RFP to implementation, the Entity Registry will take six months, and will be ready for use in early-to-mid 2011 to meet the first meaningful use incentive payment deadline.

For the Service Registry, Cal eConnect will implement a procurement and development process over the course of the next 6-12 months. The Service Registry will be made available in 2011 and would provide the state-level clearinghouse directory that interfaces with local provider directories and ultimately offers the state a seamless system for the direction of transactions.

Value-added Services

Value-added services will be evaluated over time by the Cal eConnect Board, staff and workgroups to determine their impact on organizational sustainability. Based on the recommendations in the HIE Strategic and Operational Plan, one value-added service is being considered at this time, although further planning work is taking place to fully define it:

- **Lab Services:** A value-added service that aids labs in routing results to the appropriate ordering providers and public health agencies. The service will utilize the core services to identify the appropriate providers and/or public health agencies, and might also include translation or transformation services that aid the lab in providing lab results in a format and using a protocol supported by each.

Value-added services should be developed over a 12-18 month cycle to allow Cal eConnect to determine the strategy for the provision of services that may eventually either compete in the market place with other established vendors or partner with those vendors.

Business Operations

Cal eConnect will establish the necessary business infrastructure early on to carry out its strategy and the requirements of the Cooperative Agreement Program. This includes hiring

staff, supporting organizational and programmatic policy development and implementation, contracts management and oversight capability, financial management capability and sustainability planning.

In the first six months of implementation, Cal eConnect will hire 15 full time employees to oversee the technical and business operations necessary to carry out Cal eConnect's charge, with the first hire being the CEO in July. The CEO will lead the Executive Team comprised of a Chief Financial Officer, Chief Information/Technology Officer, and Chief Operations Officer providing services oversight and management. Further detail can be found in the Business Operations Section.

Organizational policies and procedures including conflict of interest, transparency, hiring, and procurement will also be finalized in the early months using staff and workgroup support. These policies will serve as the foundation for how Cal eConnect will procure vendors, establish programmatic polices and allocate grant dollars.

Finally, a communications and stakeholder engagement plan will be refined and carried out via the workgroups with staff support. Specific activities will be carried out to coordinate strategy and timelines with key entities supporting the meaningful use of EHRs, including Medi-Cal and other State agencies, the Regional HIT Extension Centers, the California Telehealth Network with rural partners and local Health Information Exchange Organizations, among others.

Governance

The primary governance structure of Cal eConnect will be its 22-member multi-stakeholder Board of Directors, fully seated in June 2010 and meeting monthly. Four advisory workgroups will be established in June to inform the Cal eConnect strategy and advise the Board. These include the eConnect Policy, Technology, Engagement, and Business workgroups. Workgroup members, selected to represent the range of stakeholders in California, will play a vital role in defining the vendor selection process for the core services and planning for value-added services, in developing the long term business model, in engaging stakeholders in Cal eConnect's activities, and in establishing the key policies and procedures necessary to implement exchange services in California.

Legal and Policy

Much of the success of the technical architecture depends on the policies that Cal eConnect develops so that users trust the services and garner value from them. Cal eConnect must define its operational policies, align with existing State recommendations on privacy and security measures and determine how to best align with the standards suggested by the NHIN.

Where policies are not defined, Cal eConnect will use staff expert in the privacy and security of data exchange along with stakeholders in the eConnect Policy workgroup to develop and build consensus on policies. For example, Cal eConnect will need to develop requirements that govern the provisioning of entities in the core services, including a data use agreement, as well as stand up monitoring and enforcement mechanisms.

Cal eConnect will also set up a grants management and oversight mechanism to support plans to distribute funds to stakeholders in the target markets to further develop meaningful use capacity in the State and connect providers to the core services. Criteria for fund allocation and grantee selection will be developed by staff and Workgroups in partnership with other stakeholders in the coming months.

Finance

The 18-month budget from July 2010 – December 2011 includes $14.8 million in funds from the Cooperative Agreement with about one third to cover administrative costs of Cal eConnect, one third for developing the core services and one third to be distributed as grants and/or contracts to expand meaningful use infrastructure in the State and pilot Cal eConnect's services and policies. A sustainability plan will completed by February 2011 with input from the eConnect Business Workgroup to link potential revenue models to the planned services.

Conclusion

The Cal eConnect Board of Directors approved this plan for submission to the California Health and Human Services Agency on June 4, 2010 with the acknowledgement that there are remaining issues that need to be addressed prior to fully executing the plan. Further investigation and planning will occur to address the following concerns and will be reflected in a revised draft:

- Cal eConnect will need to identify longer term technology and policy solutions to be considered on its roadmap and create a process by which these solutions can be appropriately evaluated. One such solution should include the development of a patient identity management service.
- Cal eConnect will need to gather more content on the requirements to support statewide exchange infrastructure through grants and contracts. Staff and workgroups should gather data on current exchange capabilities and opportunities and develop specific requirements for grant and contract awards based on that information.
- Cal eConnect needs to further evaluate the Lab Services value-added service that is proposed in the Implementation Plan to ensure that it does not result in unintended consequences for labs and that it is designed in such a way that leverages the existing lab results routing capabilities in the State.

II. Background and Approach

This section details Cal eConnect's mission, role and process to enable meaningful use. It also introduces the market-based approach Cal eConnect is taking to define its services strategy and identify target markets.

Cal eConnect Mission and Purpose

Cal eConnect's mission is to collaboratively establish policies, services, and innovations that make possible the appropriate, secure, and efficient exchange of health information for the purpose of improving health and health care safety, quality, access, and efficiency for all Californians.

Cal eConnect is charged with convening, coordinating, overseeing and managing the implementation of HIE services throughout the state under the State HIE Cooperative Agreement Program. Cal eConnect establishes the roles, responsibilities and relationships between parties; promulgates and oversees activities among stakeholders and across State, regional and local levels; and oversees implementation of associated accountability mechanisms. Cal eConnect will coordinate its activities with the Medi-Cal EHR Incentive Program, the Department of Public Health, California Privacy and Security Board (CalPSAB) through the California Office of Health Information Integrity (CalOHII), the Rural Health Information Technology Consortium (RHITC), the California Telehealth Network (CTN), and the California Regional Health IT Extension Centers (RECs) to support achieving and demonstrating meaningful use of EHRs consistent with federal standards.

During the planning process, the stakeholders identified the following goals of Cal eConnect:

Table 1 – Goals and Implementation Milestones

Goals	Implementation Milestones – Technical	Implementation Milestones – Business Operations	Implementation Milestones - the State HIE Cooperative Agreement
1. Ensure over time that patients have safe, secure access to their personal health information (PHI), and the ability to share that information with those involved in their care.	Provide HIE services to the communities in order to achieve the Stage I Meaningful Use Criteria by 2011. Develop or facilitate the creation and use of shared directories and technical services.	Implement policies and strategies to achieve the goal with stakeholder support and community roll out of services.	Develop or facilitate the creation of a statewide technical infrastructure that supports statewide HIE
2. Engage in an open, inclusive, collaborative, public-private process that supports widespread adoption of robust EHR and HIE in the	Develop an open and transparent procurement process for Core Service development and implementation.	Establish formal work groups to provide recommendations to Cal eConnect for the policies and procedures for EHR and HIE implementation.	Establish mechanisms to provide oversight and accountability of HIE to protect the public interest.

state.			
3. Improve health care outcomes and reduce costs.		Determine evaluation measures and reporting requirements from grant funding.	
4. Maximize California stakeholders' access to critical ARRA funds.	Provide core technical services at a reduced rate to stakeholders.	Develop grant program for distribution of some funds to appropriate stakeholders for achievement of meaningful use guidelines.	Document how the HIE efforts within the state are enabling meaningful use.
5. Integrate and synchronize the planning and implementation of HIE, HIT, tele-health and Provider incentive programs under ARRA.	Offer core services to the Medi-Cal and public health entities to ensure integration of services at state government.	Develop and conduct coordination committee with CalHIPSO, Connect LA, other RECs, CTN and other HIE entities through workgroups.	Ensure the coordination, integration, and alignment of efforts with Medicaid and public health programs through efforts of the State Health IT Coordinators.
6. Ensure accountability in the expenditure of funds.	Institute an open and transparent procurement process based on competitive bidding.	Develop an evaluation and oversight committee and staff structure.	Develop the capability to effectively manage funding necessary to implement the state Strategic Plan, including establishing financial policies and implementing procedures to monitor spending and provide appropriate financial controls.
7. Develop a trusted, transparent and collaborative entity that coordinates the stakeholder implementation.	Develop workgroup focused on key stakeholder engagement and outreach.	Finalize the governance entity and workgroups structures for implementation and oversight of the plan.	Develop transparency policy that specifies Cal eConnect's how Cal eConnect will have open and transparent processes
8. Create a sustainable business model for the organization.	Develop value based core services at a reduced rate that provide ongoing revenue stream for Cal eConnect.	Develop a business model over time with a representative group of stakeholders through the eConnect Business Workgroup.	Develop a path to sustainability including a business plan with feasible public/private financing mechanisms for ongoing information exchange among health care providers and with those offering services for patient engagement and information access.

The eight goals have been prioritized in accordance with the Stage 1 Meaningful Use criteria so far identified by ONC to be achieved by July 2011. Stage 2 and 3 criteria for 2012 and beyond are not yet defined but as they develop they will be incorporated in a long-term strategic plan for Cal eConnect.

Market Based Approach

Because of the size and diversity of California's communities, Cal eConnect is taking a market-based approach to defining its strategy, dividing the State into three scenarios including Rural Communities, Urban Health Information Exchange and Unaffiliated Providers. Across each of these scenarios, staff has begun to identify the market features, requirements, opportunities and partners Cal eConnect should leverage when devising the implementation strategy.

The Three Market Scenarios

Rural Communities:

The rural health market, defined by the 43 counties identified in Appendix 2, includes an estimated 8.2 million residents, roughly 11,600 active physicians, 145 general acute care hospitals, 330 primary care clinics, and 3 operating Health Information Organizations (HIOs)[3].

Rural providers have two primary needs: access to information coming in (e.g., lab results) and transfer of information at transitions of care (e.g., clinical summaries for referrals and admissions, or discharge summaries at transfers to tertiary care or home).

Given these needs, coordination with the 3 operational HIOs, the California Telehealth Network, and the newly formed Regional Health Information Technology Coalition (RHITC) is a critical first step to providing services to this market and is a first priority for Cal eConnect. Once the readiness of each of these rural sub-markets is determined, core service technology could advance the regional efforts rapidly and efficiently.

Urban Health Information Exchange:

The urban market is defined by the remaining 15 counties in California that are non-rural and have large, concentrated populations. This market includes more than 30.4 million residents, 54,800 active physicians, 315 general acute care hospitals, 660 primary care clinics, and four operating HIOs with 5 more in the planning stages (see Appendix 2)[4]. The stakeholders in these counties are generally more advanced in EHR implementation and use, have more funding and are more involved in HIO activities that are either under development or in production.

Urban-area HIOs are organizations formed to fill a community need to move health information amongst organizations. Characteristically, these organizations are fast to adopt technology standards, such as the Nationwide Health Information Network's Clinical Care Document (CCD) implementation specifications. They are also organizations that have very lean budgets – the purchase of any technology solution is related to the amount of value created by the cost. These organizations are also typically using technology that would readily adapt to a web services style query to retrieve information from a core registry service. All of California's existing

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[3] Sources: Residents & Physicans (Fewer and More Specialized: A New Assessment of Physician Supply in California. CHCF. June 2009.); Hospitals & Clincs (Office of Statewide Health Planning and Development, Healthcare Information Division, Facility Listings. December 31, 2009.); HIOs (California eHealth Collaborative)

[4] Ibid.

community-based HIOs (and many of the Integrated Delivery Networks) are prepared to use a State registry service in order to identify the end points for delivery of secure messages of all types. Currently, HIOs are working first to increase their ability to deliver health data to providers listed in their own records. As a second step, once there is a need, statewide entity and services registry would provide a needed resource for connectivity to providers outside existing HIO and IDN networks.

Unaffiliated Providers:

"Unaffiliated providers" comprise solo practices and small group practices of five or fewer physicians. These business entities typically have limited IT resources to build and maintain data interfaces for their EHRs. To achieve interoperability with other enterprises (practices, labs, pharmacies, etc.) they generally rely on the intrinsic capabilities of their IT products and on the bundled services of their IT vendors. Hence, in the near term (1-3 years), unaffiliated practitioners will be challenged to leverage the state infrastructure services that are envisioned, because they will lack the resources to interface their EHR systems to these services.

The unaffiliated providers would likely first achieve access to connectivity through programs outside of the State HIE Cooperative Agreement Program; these programs include the CalHIPSO Regional Extension Center, HITEC-LA Regional Extension Center, the California Telemedicine Network and the Medi-Cal EHR Incentive Program. These unaffiliated providers are the lowest priority for core service offerings from Cal eConnect, but a high priority for coordination with the RECs, CTN and the Medi-Cal funded programs.

Market Strategy Framework

Cal eConnect will use a market strategy framework to further refine the setting, features, requirements and opportunities available in each of the three scenarios. This approach will help drive evidence-based decisions around the sequencing of implementation of the technology architecture and distribution of grants and contracts.

Figure 1 below shows summary market features, including the number of physicians, general acute care hospitals and existing HIO presence, for the three scenarios. Detailed research on the data exchange needs and market features and opportunities by meaningful use criteria will inform what solutions are appropriate for which scenarios and at what time. A sample conclusion from this framework is that core services should be rolled out earlier to provider organizations that are part of larger commercial entities while EHR implementation support is being provided by other entities to organizations that are less well capitalized and less capable of sophisticated infrastructure projects.

This research will continue throughout the remainder of the planning period. Specifically, we will identify by county:[5]

Market size, including number of:

- Residents
- Eligible Providers
- Eligible Hospitals
- Community Clinics
- Ancillary Service Organizations

[5] The granularity of county level data will allow Cal eConnect to be more strategic about its investments. When needed, we will aggregate data to the regional level.

- Operational HIOs and HIOs in development

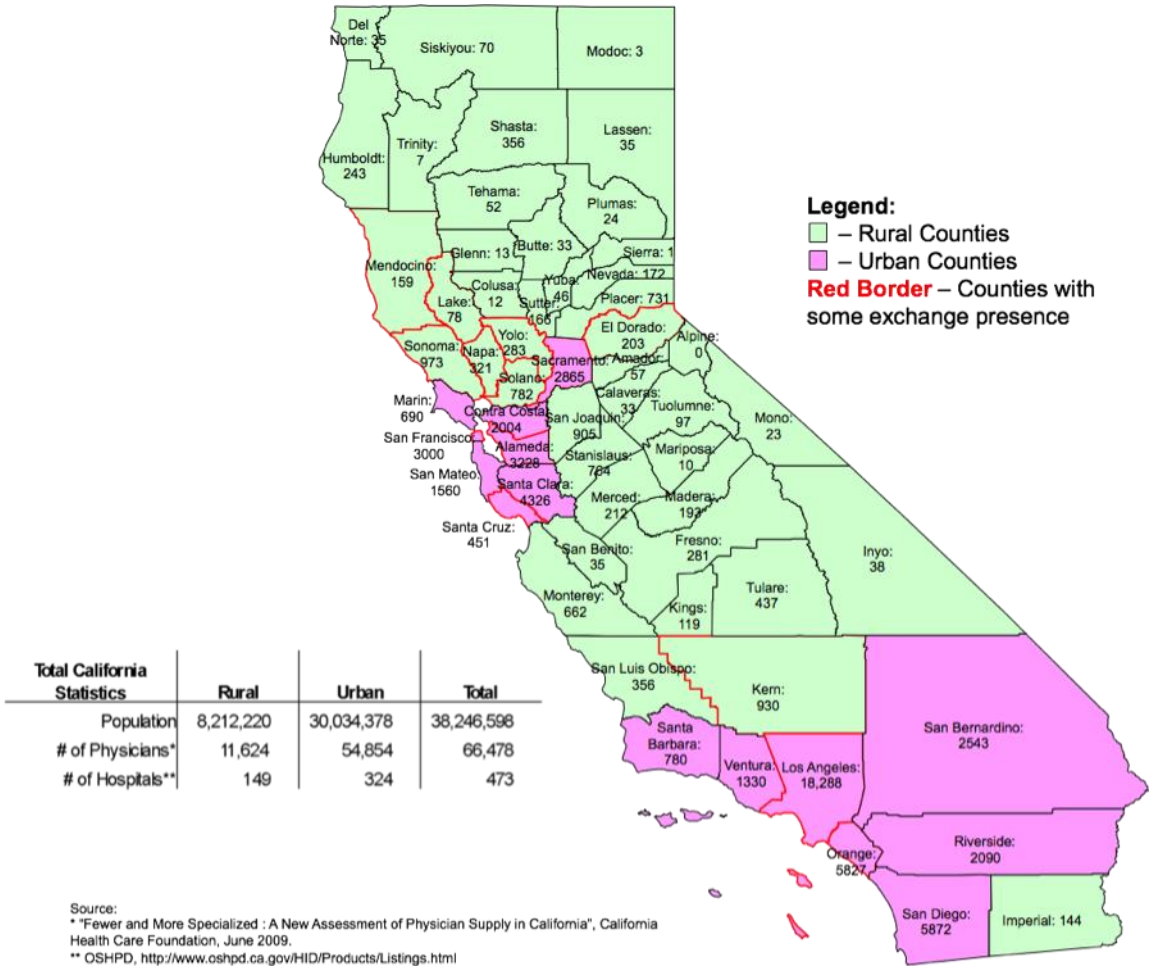
Market characteristics, including:

- Rate of patient transfers & referrals
- Amount of working capital
- Underserved and vulnerable populations
- Population density

Health IT readiness indicators, including:

- Level of IT adoption and sophistication, including rates/numbers of EHR adoption
- Integration of Lab/Rx
- Penetration of Integrated Delivery Networks
- Vendor interest
- Enthusiasm for meaningful use, including provider commitment
- Revenue potential

Figure 1: Aggregate Market Features by County and Scenario in California



Total California Statistics	Rural	Urban	Total
Population	8,212,220	30,034,378	38,246,598
# of Physicians*	11,624	54,854	66,478
# of Hospitals**	149	324	473

Source:
* "Fewer and More Specialized : A New Assessment of Physician Supply in California", California Health Care Foundation, June 2009.
** OSHPD, http://www.oshpd.ca.gov/HID/Products/Listings.html

Solutions and Implementation Approach By Market Scenario

The data gathered through the market strategy framework will identify the distinct features and capabilities of each market and inform tailored solutions and implementation requirements to enable meaningful use of EHRs. Significant work has already begun to assess the appropriate implementation approach for each scenario. This will be finalized as the Cal eConnect team further develops its strategy, including the market strategy framework and business model. See Appendix 2 of this document for work completed thus far on the market opportunities and technology implementation requirements by scenario.

Requirements for Meaningful Use and Exchange

This section highlights the requirements that Cal eConnect should address in order to enable Stage 1 meaningful use for providers and meet the general requirements of the HIE Cooperative Agreement in terms of coordination with State and Federal partners.

Meaningful Use of Health Information Technology

The HIE Strategic and Operational Plan identified the following HIE-dependent meaningful use criteria for Stage 1 incentive payments based on the current NPRM. Table 2 identifies the relevant HIE capability required in addition to the specific technical components needed to enable the exchange. These components are described in more detail in the following sections of this plan.

Table 2: Stage 1 Meaningful Use Criteria for which HIE is Essential

Meaningful Use (MU) Criteria	Relevant HIE Capability	Technical Components Needed for MU*
1. Generate and transmit permissible prescriptions electronically	Infrastructure for an EHR or EHR module to correctly address and securely transmit an electronic prescription to the desired dispensing pharmacy in the specified standard format. The transmission may occur directly or via a third party.	• Entity & Service Registry
2. Incorporate clinical lab-test results into EHR as structured data	Infrastructure for labs to securely transmit structured lab results to the EHR or EHR module of the appropriate provider(s) in the specified standard format. The transmissions may occur directly between labs and EHRs or via a third party.	• Lab Services
3. Check insurance eligibility electronically from public and private payers	Infrastructure to securely query a payer, either manually via a web browser or automatically via Electronic Data Interchange (EDI), in the specified standard format and to receive an electronic response, either via a web browser or automatically via EDI, in the specified standard format. These transactions may occur directly between providers and payers or via a third party.	• Entity & Service Registry • Messaging Framework • Authorization Framework

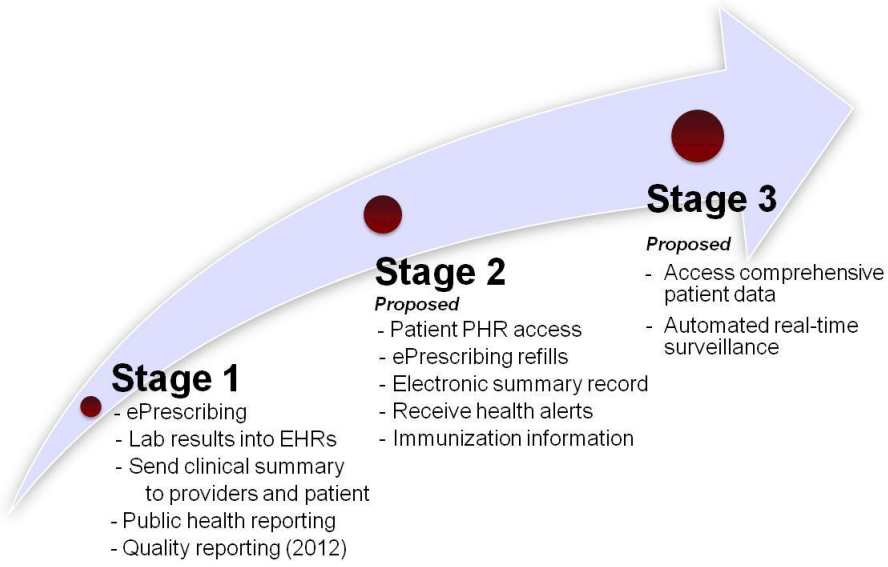
Meaningful Use (MU) Criteria	Relevant HIE Capability	Technical Components Needed for MU*
4. Submit claims electronically to public and private payers	Infrastructure to securely transmit claims from a provider organization to a payer in the specified standard format. These transactions may occur directly between providers and payers or via a third party.	• Query and Response Exchange and Information Submission Specifications • NHIN Gateway • Messaging Framework • Authorization Framework
5. Provide patients with an electronic copy of their health information / discharge instructions upon request	HIE capability is required if the electronic copy is transmitted to the patient via a network, either directly (e.g., via secure email) or through a third-party patient-authorized entity (e.g., a Personal Health Record (PHR)). In these cases, the capability is required to correctly address and securely transmit the information in an accepted format to the patient or the patient-authorized entity.	• Entity & Service Registry • Patient Discovery Specifications
6. Provide patients with timely electronic access to their health information within 96 hours	HIE capability is required if electronic access is provided to patients via a third-party patient-authorized entity, such as an "untethered" PHR or secure messaging service.	• Entity & Service Registry • Patient Discovery Specifications
7. Capability to exchange key clinical information among providers of care and patient-authorized entities electronically	Infrastructure to correctly address and securely transmit the specified types of information (problem list, medication list, etc.) in an acceptable data format from one provider to another, from a provider to a patient-authorized entity, or from a patient-authorized entity to a provider.	• Service Registry • Messaging Framework • Trust Framework • NHIN Gateway
8. Provide summary-of-care record for each transition of care and referral	HIE capability is required if (1) the transition of care or referral is made to a different organization and (2) if the summary-of-care record is communicated in electronic format over a network. In this case, the capability is required to correctly address and securely transmit the record to the new or referred site of care in a specified data format.	• Entity Registry
9. Capability to submit electronic data to immunization registries and actual submission where required and accepted	Infrastructure to securely transmit immunization events from any hospital or outpatient facility to the appropriate immunization registry for the appropriate patient in a specified data format	• Entity & Service Registry
10. Capability to provide electronic submission of reportable lab results to public health agencies and actual submission where it can be received	Infrastructure to securely transmit lab results from any hospital laboratory to the appropriate public health agency in a specified standard format (including required de-identification of the data)	• Lab Services

Meaningful Use (MU) Criteria	Relevant HIE Capability	Technical Components Needed for MU*
11. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Infrastructure to securely transmit relevant clinical data from any hospital or outpatient facility to the appropriate public health agency in a specified standard format (including required de-identification of the data)	• Provider Registry
12. Report ambulatory quality measures to CMS or states	Accurate generation of ambulatory quality measures may require the electronic aggregation of clinical data from multiple organizations (as above). In this case, the same HIE capability is required as for #8 above.	• Entity & Service Registry

*Note: These components are derived from the functional requirements needed for each Meaningful Use (MU) criteria. They represent the foundational components that must be built to enable secure exchange. Cal eConnect will identify additional components and services needed to enable MU in the future.

Meaningful Use - Stages 2 and 3

Achieving the meaningful use criteria in Stage 1 is well covered throughout this implementation plan. The criteria for Stages 2 and 3 are still under development by CMS and will not be provided in time for the submission of this plan. However, with the outline pictured below, Cal eConnect can begin to plan for the expansion of Core Services and contracts with the remaining funds in order to enable more comprehensive data exchange.



For example, California has 11 immunization registries. The sharing of immunization records using Health Level Seven International (HL7) messaging has been technically challenging to registries nationwide despite considerable, ongoing effort. With the exception of registries in one county, California's regional immunization registries do not currently have the capacity to accept immunization data via HL7 messaging directly from EHRs.

As a Stage 2 priority, Cal eConnect must develop a plan to address the use of registries and the current system in place in California to coordinate this meaningful use capability for non-clinic providers who do not currently access this system.

Other items on Cal eConnect's planning roadmap will include identity management, decision support, clinical summary document routing, and other potential value-added solutions that will drive improved coordination and quality of care. The market strategy work described in the previous section will inform planning in terms of what solutions are already being addressed in the market and what value-added role Cal eConnect should play. Cal eConnect will also use a stakeholder workgroup, the eConnect Technology Workgroup, to review and recommend these value-added services to the eConnect Business Workgroup and the Board for consideration.

Other National and State-level Requirements

ONC has stated that it expects a significant portion of the funds available through the State HIE Cooperative Agreements Program to be used to facilitate exchange with federal agencies and other states. At this time, it would appear that the federal Nationwide Health Information Network (NHIN) Exchange is the preferred mechanism for exchange with federal agencies. Given ONC's requirement, NHIN Exchange may well become the preferred mechanism for exchange with other states.

The federal Nationwide Health Information Network (NHIN) Exchange currently connects a diverse set of federal agencies and private organizations that need to securely exchange electronic health information. These entities currently include the Social Security Administration, MedVirginia, the Department of Veterans Affairs, the Department of Defense, and Kaiser Permanente.

At this time, non-federal entities can only participate in the Exchange through a federally sponsored contract that pertains to NHIN implementation. Federal agencies are assessing and prioritizing their rollout strategy and will prioritize their expansion over the next 12 to 18 months. It is clear that the federal agencies will use NHIN Exchange moving forward. Organizations such as the DoD, VA, and CDC are moving away from previous solutions for health information exchange to utilize Exchange instead. CMS has at least four initiatives in conceptual or pilot stages that will utilize NHIN as a preferred method of electronic exchange – one of them the receipt of aggregated quality measures, a meaningful use criteria.

Therefore, it may be appropriate to include full technical capabilities to participate in NHIN Exchange as a requirement for statewide exchange.

III. Technical Architecture

This section explains the initial strategy for statewide services to support meaningful use based on the recommendations in the HIE Strategic and Operational Plan and details the process for implementing the strategy, including how Cal eConnect will choose to build and operate the statewide architecture.

Highlights: In the first 12 months, Cal eConnect will develop the standards and specifications necessary to support the core infrastructure and will procure vendors to build the software components. The initial core services will support two functions critical to enabling meaningful use, allowing entities to (1) positively identify each other as trusted and (2) determine where and how to exchange information securely. Cal eConnect will make these services available to customers prior to the July 2011 meaningful use deadline. Other value-added services will be considered for future rollout, with the first candidate being Lab Services to support the routing of structured lab results.

Key Tasks and Timeline from Work plan:

Key Tasks and Deliverables	Target Completion
Identified statewide architecture for shared services into components	Completed
Evaluated that meaningful use criteria are addressed in technology solutions	Completed
Conduct Resource Assessment	Completed
Developed Messaging and Authorization Framework	August 2010
Assess necessity of additional specifications (Patient Discovery Specification, Query and Response Exchange Specification, Information Submission Specification)"	August 2010
Developed Entity Registry	May/June 2011
Developed Service Registry	June/July 2011
Value-added Services - Developed Lab Services	TBD
Technology Rollout	TBD

Technology Strategy

Based on the recommendations in the HIE Strategic and Operational Plan, Cal eConnect designed its technology strategy to align with the meaningful use criteria (the primary basis for our technology requirements), NHIN standards and capabilities, and California privacy and security guidelines.

The following paragraphs summarize these inputs to the technology strategy and detail a prioritized list of functionality from which the architecture was designed. For a complete explanation of the technology strategy, see Appendix 3. The architecture for statewide shared services is described in the next section and is detailed in Appendix 4.

Infrastructure Components Derived from Meaningful Use

Supporting eligible providers in achieving meaningful use was viewed as the priority for developing the initial functional capabilities of statewide HIE services.

To meet this priority, Cal eConnect used the meaningful use criteria associated with HIE to identify the relevant HIE capability and related functional requirements (see Table 2 for the

mapping of meaningful use criteria to infrastructure components). The functional requirements were then translated into technical requirements. The technical requirements allowed us to identify a set of infrastructure components for statewide services. This process is detailed in Section 2.1 of Appendix 3. The resulting infrastructure components comprise a "trust architecture" to allow for secure and authenticated transactions. The table below shows how the proposed infrastructure components relate to the technical requirements derived from meaningful use.

Table 3 Tracing planned infrastructure components to technical requirements derived from meaningful use criteria

Technical Requirements Derived from Meaningful Use	Infrastructure Component
a standards-based message framework for secure and reliable exchange	*Messaging Framework*
a trust framework for authorization and consumer consent	*Authorization Framework*
a standards-based interface to a root certificate authority that "authenticates" an entity or individual	*Entity Registry*
a digital certificate authority that is supported by a standards-based interface and supporting the messaging framework and trust framework	
a standards-based interface to a directory of all entities participating in exchange	*Entity Registry* and *Service Registry*
a directory of entities participating in exchange	
a standards-based interface to a directory of providers participating in exchange	*Service Registry*
a directory of providers participating in exchange	
a standards-based service specification for discovering patient identities and agree on shared identities	*Patient Discovery Specification*
a standards-based service specification for (1) a push exchange pattern, (2) a query and response exchange pattern, and (3) a publish and subscribe exchange pattern	*Query and Response Exchange* and *Information Submission Specifications*
a gateway interface to the Nationwide Health Information Network	*NHIN Gateway*

National Standards and Capabilities

The NHIN is a set of services, standards, and policies being developed by ONC that enable secure exchange of health information over the Internet to connect providers, consumers, and others involved in supporting health and healthcare. NHIN has two projects—the NHIN Exchange and NHIN Direct. NHIN Direct was developed to explore standards and services required to enable HIE at a more local and less complex level.

NHIN Exchange has defined a messaging framework, authorization framework, and patient consent conventions that meet many of the needs of our Messaging Framework and Authorization Framework, and may be used as a model. NHIN Direct is in the process of developing an alternative to the NHIN Exchange messaging framework that may also inform the detailed development of the Messaging Framework.

NHIN Exchange has also defined web service specifications for patient discovery and query/response exchange patterns that may meet the needs of statewide exchange for Patient Discovery and Query and Response Exchange. Both NHIN Exchange and NHIN Direct are developing web service specifications for a push pattern that could be used for Information Submission.

NHIN has also done extensive work on data sharing, privacy and security requirements that can be leveraged. Cal eConnect should use NHIN work as a model when possible and move beyond it when it does not meet requirements, including the development timeline. Additional information on NHIN is available in Sections 2.2, 2.3, 3.1 and 3.2 of Appendix 3.

California Security and Privacy Guidelines

The California Privacy and Security Advisory Board (CalPSAB), established by the California Office of Health Information Integrity (CalOHII), has formulated a set of recommendations regarding privacy and security guidelines for exchanging health information under the State HIE Cooperative Agreement Program. In certain cases, these guidelines go well beyond the criteria for HIE set forth in the draft rule for meaningful use and in the Health Information Portability and Accountability Act (HIPAA), making it important to consider them in planning an HIE infrastructure in California.

In particular, State policy on privacy and security will inform the development of the Messaging Framework and Authorization Framework. Development of those policies should take priority, as all technical solutions are based upon the specifications for the Message Framework and Authorization Framework. More detail can be found in the Legal and Policy section of this plan in addition to Section 3.3 of Appendix 3.

Components of Technology Strategy

Taking into account the inputs above, Cal eConnect's overall technology strategy for statewide services should include the following key components:

1. The strategy is based on a service-oriented approach to system design using the Internet.
2. The strategy includes the development of technical specifications and software components required for meaningful use
3. The software components may be separated into so-called "core components" that comprise the infrastructure for statewide HIE and so-called "business components" that provide value-added services.
4. Policy must inform the development of the messaging framework and authorization framework specifications.
5. The core components implement the messaging framework and authorization framework specifications.
6. The services and standards developed for NHIN Exchange should inform the development of the statewide infrastructure and be utilized and leveraged where possible.

Section 4.2 of Appendix 3 goes into greater detail as to how these components are reflected in the system architecture.

Prioritizing the Functional Capabilities

Unless CMS makes significant alterations in the draft rule for meaningful use, no provider can qualify for incentives without demonstrating all criteria to some degree. However, it suggests that some functional capabilities in our proposed architecture have a higher priority than others in demonstrating value to providers and therefore value in being included in the statewide exchange services.

1. All meaningful use criteria require authentication and network location of entities receiving information or queries for information. This suggests that a technical solution to these requirements – a digital certificate authority and entity registry – might occupy the highest priority.
2. Secure information submission is required for more meaningful use criteria than other exchange patterns. Development of the specification for this capability might occupy a high priority.
3. Most criteria require the network locations of systems and entities rather than individual providers. Therefore, directory services that identify entities might be prioritized to proceed those that identify providers to better demonstrate value.
4. Secure information feeds supports only a single meaningful use criteria – syndromic surveillance – that might also be supported by secure information submission. A specification for it therefore might be dropped from the list of technical requirements, or at least put at the lowest of priorities.
5. An NHIN gateway is likewise only required by a single meaningful use criteria – submission of quality measures. However, access to NHIN may be required to meet the requirements of the State HIE Cooperative Agreement Program to exchange information with federal agencies and other state HIEs.

These priorities dictate an initial architecture that builds trust among participants and applies across the spectrum of information exchange, market scenarios and meaningful use criteria. As the market needs advance and the other inputs change, Cal eConnect will revise its strategy and will build on the foundational architecture described in the following section.

Technical Architecture Overview

Based on the technology strategy, which linked possible infrastructure components to meaningful use, and prioritized functionality, Cal eConnect proposes to develop a statewide architecture for shared services divided into three areas:

1. *State Infrastructure for Core Services* is a minimal set of technical resources that enable statewide exchange. This infrastructure establishes a secure and reliable basis for HIE compliant with State policy and enabling meaningful use. It is composed of:
    a. Specifications (a messaging framework and authorization framework)
    b. Software components (entity and service registry services) that comply with the specifications of the messaging framework and authorization framework
2. *Discovery and Exchange Service Specifications* form the technical interface details for set of standards-based mechanisms that can be used by organizations to locate and exchange information on a statewide basis. The use of these service specifications may be optional, based on policy yet to be determined.
3. *Value-added Services* that provide an expanding set of value-added software services that enable higher-level business processes. While not required by meaningful use,

Business Services provide the heavy lifting that reduces the burden on organization in exchanging data and realizing value in achieving meaningful use.

In the next two sections, we further describe the architecture components, the implementation strategy, and resource requirements for both the State Infrastructure for Core Services and the Value-added Services. As the discovery and exchange service specifications are optional, the discussion is made available in Section 4 of Appendix 4. For a complete summary of the technology architecture, including a detailed discussion of specifications, see Appendix 4 and the addendum to this document, titled "Draft Technical Specifications for Core Services".

Scenarios Illustrating Portions of the Architecture

Before describing the implementation strategies and resource requirements, it is useful to illustrate how the proposed architecture will enable the exchange of health information.

Scenario using Core Services: A lab (an Entity) wishes to use its lab information system to send a structured lab result to the EHR used by a specific provider identified in the lab order. To do this, it uses:

1) the service registry (a software component of the State Infrastructure) to identify a web service address for the recipient provider's EHR and a definition of the protocol used to send information to it;
2) the entity registry (a software component of the State Infrastructure) to create a secure, encrypted, and validated connection to the EHR; and
3) a standards-based service to exchange the information; perhaps one identified by a mandatory Exchange Service Specification.

To achieve this exchange, the lab system takes responsibility for creating structured lab result content. Cal eConnect takes responsibility for supporting the lab in locating the provider's EHR on the network and establishing a secure, encrypted connection to that and only that EHR. The provider's HIO or EHR vendor takes responsibility for incorporating the structured lab result content into the EHR.

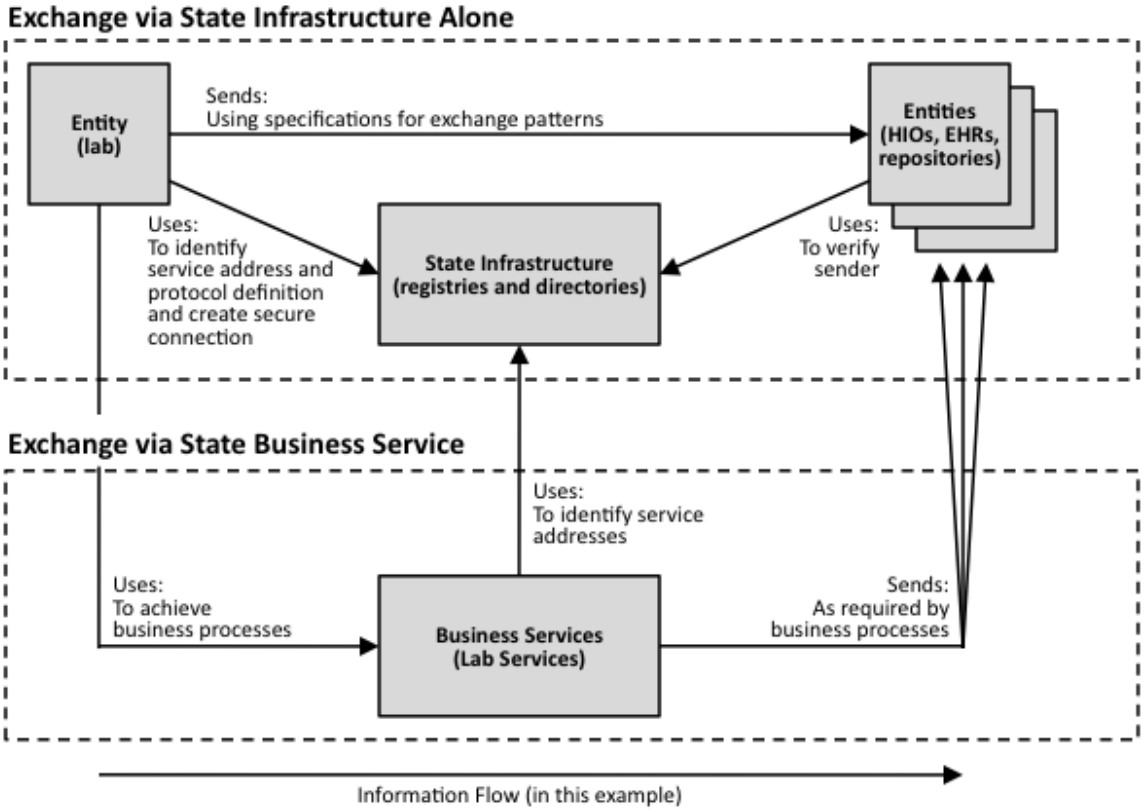
Scenario using Value-added Services: Alternatively, the lab could send a structured lab result to a clearinghouse (Business Service) along with intended recipients of that result, such as the ordering specialist and primary care provider. The clearinghouse in turn:

1) uses the service registry (a software component of the State Infrastructure) to identify a web service address for the specialist provider's EHR and the primary care physician's EHR, and definitions of the protocols used to send information to them, which may be different;
2) determines whether the result is to be reported to public health, and if so, uses the service registry to identify a web service address the public health reporting system and a definition of the protocol used to send information to it;
3) translates the structured lab result into the terminology used by each system and transforms the format into the standard used by each system, again all of which may be different;
4) removes identifying information from the message bound for the public health system, if required;
5) uses the entity registry (a software component of the State Infrastructure) to create secure, encrypted, and validated connections to both EHRs and the public health system in turn; and

6) uses standards-based services to exchange the information with each system, in turn; perhaps using services identified by mandatory Exchange Service Specification.

While the process utilized by the Business Service is clearly more complex, it also illustrates how the burden on the lab and its Laboratory Information System (LIS) can be relieved using Business Services. In order to achieve this exchange, the lab system still takes responsibility for creating structured lab result content. The Business Service orchestrates the complex business process for lab results delivering. Cal eConnect takes responsibility for supporting the Business Service in locating and connecting the provider's EHRs and public health system on the network and establishing secure, encrypted connections. The provider's HIO or EHR vendor and public health agency take responsibility for incorporating the structured lab result content into the EHRs and public health systems, respectively.

The figure below provides a high-level view of the technical interactions described in these scenarios.



State Infrastructure for Core Services

This section describes the architecture components, the implementation strategy, and resource requirements for the State Infrastructure for Core Services—the minimal set of technical resources that enable statewide exchange. The State Infrastructure is managed, overseen, regulated and/or financially supported to some extent by Cal eConnect under the State HIE Cooperative Agreement Program.

The State Infrastructure consists of: the Messaging and Authorization frameworks, which describe standards and specifications by which the software components will operate; the Entity Registry software, which creates secure, encrypted, and validated connections for sharing

health information; and the Services Registry software, which details how and where to send protected health information.

Messaging Framework and Authorization Framework

The two specifications that establish the framework for secure web services (and implement patient consent) are detailed below:

- *Messaging Framework*: Specifications for the basic exchange of information over the Internet, the messaging framework is based on web services following recognized national standards. It includes specifications for the web service standard, acceptable encryption standards, and the use of digital certificates to establish secure, reliable, encrypted exchange.
- *Authorization Framework*: Specifications for how entities assert authorization for information requests, and how those assertions are carried within the Messaging Framework. The Authorization Framework must identify how the key requirements of CalPSAB authorization and access controls are addressed, including how to represent the data source, entity of requestor, role of requestor, use of data, sensitivity of data, and consent directives of the data subject are addressed. The Authorization Framework must enable both State and NHIN policies associated with patient consent.

Implementation Strategy

As the governance entity for the statewide exchange and manager of the State Infrastructure, Cal eConnect should take responsibility for developing the specifications for the Messaging Framework and Authorization Framework. A detailed discussion of the basic standards and behavior dictated by the Messaging Framework and Authorization Framework is located in Section 3.1 of Appendix 4.

Details of the specification should be defined through an open and transparent process that includes stakeholders throughout the State. There exist several models for standards development, including perhaps the Internet Engineering Task Force (IETF), the World Wide Web Consortium (W3C), and IHE. An analysis of the commonalities among these three recommends a set of best practices that include:

1) An open, inclusive process including input from a board industry cross-section, not only for public comment, but likewise for the drafting of new specifications.
2) A controlled, transparent mechanism for prioritizing development of new specifications and advancing them through the development process.
3) A managed and documented model for the maturity of a developing specification that defines the roles of all participants at each stage of development.
4) A process to subject specifications to implementation testing to assess whether a specification is complete and can be implemented.

The development of these specifications must be preceded by definition of the policies that define privacy and security, and the role and process for patient consent.

Resource Requirements

The model for the Messaging Framework and Authorization Framework are based on those of NHIN Exchange and are compliant with ONC requirements for standards and certification identified in the Interim Final Rule (IFR) for EHR Certification. As such, it should be possible to complete this action through a minimal technical staff working with in conjunction with working

groups comprising volunteers from the stakeholder community in working groups and in a short period of time.

Specifications development should be managed part time by a CTO or Systems Architect on staff with Cal eConnect (perhaps 20% effort) over a 2-month period, utilizing one full-time technical writer or consultant to manage workgroup(s), draft the specifications, and review public comments. The workgroups in turn comprise volunteers from the community.

The process will require the use of web sites to publish drafts and collect comments (perhaps using a wiki or other Web 2.0 mechanism), and web-based meetings to facilitate the workgroups.

Entity Registry

Before describing the Entity Registry further, it is useful to define an Entity and a Node:

> *Entity*: A legal business entity that assumes responsibility for safeguarding the patient health information under its control and for managing in a secure manner the exchange of protected health information (PHI). Entities may be physician practices, hospitals, clinics, pharmacies, health plans, state or federal agencies, IDNs, health systems, HIOs, or other organizations. The responsibilities of Entities include ensuring that their users are reliably authenticated when they request access to PHI that is controlled by other entities, and reliably authorizing access to the PHI they control when requested by other Entities.
>
> *Node*: A health IT system that exists on the Internet and implements services that participate in statewide HIE in accordance with the messaging framework and authorization framework. Nodes may include EHRs, practice management (PM) systems, lab information systems (LISs), immunization registries, public health reporting and surveillance data warehouses, personal health records (PHRs) or patient-controlled health records (PCHRs), health plan claims and eligibility systems, etc. Nodes are not equivalent to Entities, but are operated by them. Entities take responsibility for Nodes and a single Entity may operate one or more Nodes.

The Entity Registry is a trusted registry of Entities engaged in statewide exchange and the Nodes or systems for which they are responsible. The Registry serves to ensure parties engaged in exchange of the validity and authenticity of exchange partners. It also provides the primary control point for the State to enforce policies associated with health information exchange. Only Entities and Nodes with valid entries in the Entity Registry can exchange information using statewide services.

Functionally, the Entity Registry contains listings of the Entities and Nodes that are participating in exchange, along with a unique identifier and a digital certificate for each. Digital certificates associated with Entities are used to sign assertions of authorizations in compliance with the Authorization Framework. Digital certificates associated with Nodes are used to establish secure, encrypted connections with other Nodes in compliance with the Messaging Framework, validating the identity of each Node, and ensuring that exchange is completed without corruption or alteration.

The Entity Registry therefore comprises:

1. a store for Entity and Node information and the digital certificates associated with them, and
2. standards-based interfaces to that store.

It is similar in structure and function to the certificate authority of NHIN Exchange, although unlike NHIN, it provides for Entities and Nodes to each have their own certificates. In the NHIN paradigm, Nodes sign authorizations on behalf of the Entity and there is no separation between the certificates and verification associated with encrypted connections and certificates exchange authorization. This limitation has proven an issue when multiple Entities share a Node or perhaps when a single Entity has multiple Nodes.

Additional details regarding the Entity Registry are provided in Section 3.2 of Appendix 4.

Implementation Strategy

As the governance entity for the statewide exchange and manager of the State Infrastructure, Cal eConnect should take responsibility for developing the specifications for and operating the Entity Registry. As the Entity Registry is the primary enforcement point for compliance with State policies and agreements, Cal eConnect should develop rigorous processes for

- provisioning and monitoring organizational compliance with its policies,
- mechanisms for addressing complaints by stakeholders, and
- a rapid process for certificate revocation to ensure that trust in the State Infrastructure is not compromised.

Details of the specification for the Registry and its interfaces should be defined through an open and transparent process that includes stakeholders throughout the State, similar to that outlined for the Messaging Framework and Authorization Framework.

The Entity Registry conforms to the Messaging Framework specification, and therefore must be defined in detail after the Messaging Framework is complete.

The Entity Registry is based on well-established industry standards for certificate repositories. A technical solution is available from several vendors. The Entity Registry therefore should be procured through a competitive procurement as a solution to be operated by Cal eConnect or a service provided to Cal eConnect.

Resource Requirements

The model for the Entity Registry is based on industry standards and is compliant with ONC requirements for standards and certification. As such, it should be possible to complete the development of the Entity Registry specification through a minimal technical staff working with volunteers from the stakeholder community – much like the specifications for the Messaging Framework and Authorization Framework.

Specifications development should be managed part time by a CTO or Systems Architect on staff with Cal eConnect (perhaps 20% effort) over a 2-month period following completion of the Messaging Framework specification, utilizing one full-time technical writer or consultant to manage the workgroup, draft the specifications, and review public comments.

The process will require the use of web sites to publish drafts and collect comments (perhaps using a wiki or other Web 2.0 mechanism), and web-based meetings to facilitate the workgroups.

The procurement will require a consultant to draft the RFP under the oversight of a CTO over the course of two months, including approval by Cal eConnect, one month to answer questions on the RFP and collect responses, and two months to review and award a contract. The review process should likewise be overseen by the CTO, and include perhaps six other reviewers selected to provide wide stakeholder representation.

It should be possible to implement the Entity Registry within three months, with oversight by the CTO part-time, and management by a full-time project manager.

Service Registry

The Service Registry provides information about how and where to direct information intended for specific individuals or systems, such a providers or their specific EHRs, and how to formulate the transactions such that they can be correctly processed when received.

Functionally, the Service Registry contains mappings between individuals or network resources (services or systems) and web service addresses and protocols. It is the primary directory that Nodes use to locate recipients of health information or queries for health information.

The Service Registry therefore comprises

1. a store with information such as location, type of organization, type of information exchange supported, etc, that can be used to locate entries using a search. Entries in the store can include providers, physician practices, hospitals, hospital departments, laboratories, pharmacies, personal health records, immunization registries, payers, and any other group to whom health information could be legitimately sent or from whom health information could be requested.
2. standards-based interfaces to that store.

A search for an entry in the Service Registry returns web service information, such as the Entity and Node identifiers used in the Entity Registry, a web service address to be used in accessing the service, and the protocol to use.

Physically, the Service Registry is a federated store. Local Service Registries may exist at and be managed by individual Entities. The State will operate a central Service Registry for those Entities that do not wish to operate one themselves. A component of the central Service Registry is an interface that, if used, performs a search of the information on all Service Registries, including all local Registries. Using this approach, a user of the Service Registry need not know the Entity associated with a provider or other network resource in order to locate it. However, it still provides a mechanism for individual Entities to manage the information associated with their systems and users, including identifying information of individual providers.

The Service Registry could conform to the Uniform Universal Description, Discovery and Integration (UDDI) XML-based registry standard for Internet service directories. A UDDI entry includes “White Pages” that include address, contact, and known identifiers, “Yellow Pages” for industrial categorizations based on standard taxonomies, and “Green Pages” with technical information about services exposed by the Entity.

The Service Registry supports the Messaging Framework by providing the web service address locations and protocols necessary to establish connections.

Additional details regarding the Service Registry are provided in Section 3.3 of Appendix 4.

Implementation Strategy

Cal eConnect will take responsibility for developing the specifications for and operating the centralized portion of the federated Service Registry as the governance entity for the statewide exchange and manager of the State Infrastructure. Cal eConnect should develop rigorous policies and process guidelines that stakeholders will use in provisioning their respective service registries, and for monitoring organizational compliance with its policies, mechanisms for addressing complaints by stakeholders.

Details of the specification for the interactions between local Service Registries and the central service, and between the central service and service users should be defined through an open and transparent process that includes stakeholders throughout the State, similar to that outlined for the Messaging Framework and Authorization Framework.

The Service Registry conforms to the Messaging Framework and Authorization Framework specifications, and the specification for it therefore must be defined in detail after the Messaging Framework and Authorization Framework are complete.

The Service Registry is based on well-established industry standards. However, its organization as a federated repository is not common. Technical solutions for a federated UDDI service registry has been proposed using several methods, and an update to the UDDI specification has recently been made specifically to address registry federation. Several vendors and systems integrators have experience in developing UDDI registries and should have the capability to develop a federated solution. The Service Registry therefore should be procured through a competitive procurement as a solution to be operated by Cal eConnect or a service provided to Cal eConnect.

Resource Requirements

The model for the Service Registry is based on industry standards and is compliant with ONC requirements for standards and certification identified in the IFR. However, the Service Registry constitutes a more complex component than the Entity Registry due to the need for it to be federated. Sufficient time must be allocated to develop the full design and specification for the service and registry.

It should be possible to complete the development of the Service Registry specification through a small technical staff working with volunteers from the stakeholder community – somewhat more robust that that for the Entity Registry. Specifications development should be managed part time by a CTO on staff with Cal eConnect (perhaps 50% effort) over a 4-month period following completion of the Authorization Framework specification, utilizing one full-time system architect on staff with Cal eConnect or retained as a consultant and one full-time technical writer or consultant to manage the workgroup, draft the specifications, and review public comments.

The process will require the use of web sites to publish drafts and collect comments (perhaps using a wiki or other Web 2.0 mechanism), and web-based meetings to facilitate the workgroups.

The procurement will require a consultant to draft the RFP under the oversight of a CTO and with advice from the system architect over the course of two months, including approval by Cal eConnect, one month to answer questions on the RFP and collect responses, and two months to review and award a contract. The review process should likewise be overseen by the CTO, and include perhaps six other reviewers selected to provide wide stakeholder representation plus the system architect involved in developing the specification and RFP.

Implementation should be accomplished within six months, with oversight by the CTO, part-time, and management by a full-time project manager and half-time security specialist.

Due to the federated nature of the Service Registry, the specification should be published as soon as possible. Individual organizations that do not wish to use the centralized registry storage operated by the State can develop their local Service Registries in parallel with the procurement process for the centralized service. It should be expected that some local Service Registries can come on line prior to completion of the centralized repository and service procured by the State, providing some initial capabilities for the State Infrastructure prior to full operational capacity of the Service Registry.

Value-added Services

In addition to the State infrastructure described above, providers may be supported in achieving meaningful use through additional value-added business services. These services would be layered on top of the State infrastructure and developed and offered on an as-needed basis over time.

The purpose of these services is to enable complex business processes, perhaps by orchestrating complex interactions on behalf of an Entity or individual. The HIE Strategic and Operational Plan and the analysis of meaningful use identified a number of higher-level value-added services as candidates for value-added services. Table 4 below outlines some of the value-added services from that analysis.

Table 4 Summary of high-level value-added services that are not required for Stage 1 meaningful use, but might have value to stakeholders.

Meaningful Use Criteria	Potential Value-added Functionality
• Lab results delivery • Public health reporting • Public health surveillance	Translation service that facilitates translating structured lab results into standard format(s)
	Clearinghouse as a single delivery point for lab systems that facilitates routing of lab results to appropriate provider systems and/or public health departments
• Eligibility verification	Clearinghouse as a single access point for EHRs and practice management systems for insurance eligibility information via EDI transactions across various health plans
• Provide copies to patients • Provide patient access	Widespread secure messaging system to enable patients and providers to communicate electronically.
• Exchange among providers • Summary at care transition	Translation service that facilitates translating and transforming among standardized summary clinical formats.
	Clearinghouse as a single delivery point for EHRs for routing clinical summary documents among providers and patient-designated entities.
• Submit immunizations	Clearinghouse as a delivery point that can accept immunization messages from EHRs and forward them to the intended immunization registry.
• Public health reporting • Public health surveillance	Utility service to manage pseudonymization and re-identification when required.

Implementation Strategies

Value-added services may be governed, developed, and operated by Cal eConnect, or may be developed, operated, and offered by third parties under Cal eConnect governance. Below are some potential business models:

1) Cal eConnect might procure development and integration services from a vendor, software developer, or systems integrator, and have the service delivered to Cal eConnect and operated as a continuing source of revenue.

2) Cal eConnect might procure the service to be developed and operated by a vendor or systems integrator, and simply govern its operation, perhaps for a small transaction or access fee.
3) Cal eConnect might support a local stakeholder, such as an HIO, through a grant to expand an existing service to extend it to the entire State.
4) A vendor with an existing solution may approach Cal eConnect or be solicited by Cal eConnect with a business model to offer the service in collaboration with the State.

All Value-added Services must conform to the Messaging Framework and Authorization Framework and will be provided entries in the Entity Registry and Service Registry.

Additional detail is provided in Section 5 of Appendix 4.

Lab Services

Of the proposed value-added services, the California eHealth Technical Advisory Committee (TAC) prioritized the development of Lab Services:

- *Lab Services*: A value-added service that aids labs in routing lab results to the appropriate ordering providers and public health agencies. This service would ostensibly replace the numerous point-to-point connections among laboratories, EHRs, and public health databases with a single routing hub connected to participating entities. It would utilize the Service Registry to identify the appropriate provider EHRs and/or public health agency data warehouses for delivery, and might also include translation or transformation services that aid the lab in providing lab results in a format and using a protocol supported by each.

A more detailed description of the how the Service could function, including the interaction of the Lab Service with the State Infrastructure, is provided in Section 5.1 of Appendix 4. Section 5.1 also includes a discussion of possible implementation strategies and resource requirements that are dependent on the specifications and functionality of the Lab Services. The actual specifications and functionality of the Lab Services will be developed through the work of a Lab Services Task Group under the eConnect Technology Workgroup.

IV. Business Operations

This section identifies the business structures and procedures Cal eConnect will set up to carry out its objectives, including *Staffing, Organizational Policies and Procedures, Updating the Strategic and Operational Plans (with Business and Sustainability Plans),* and *Carrying out the Communications and Stakeholder Engagement Plan.*

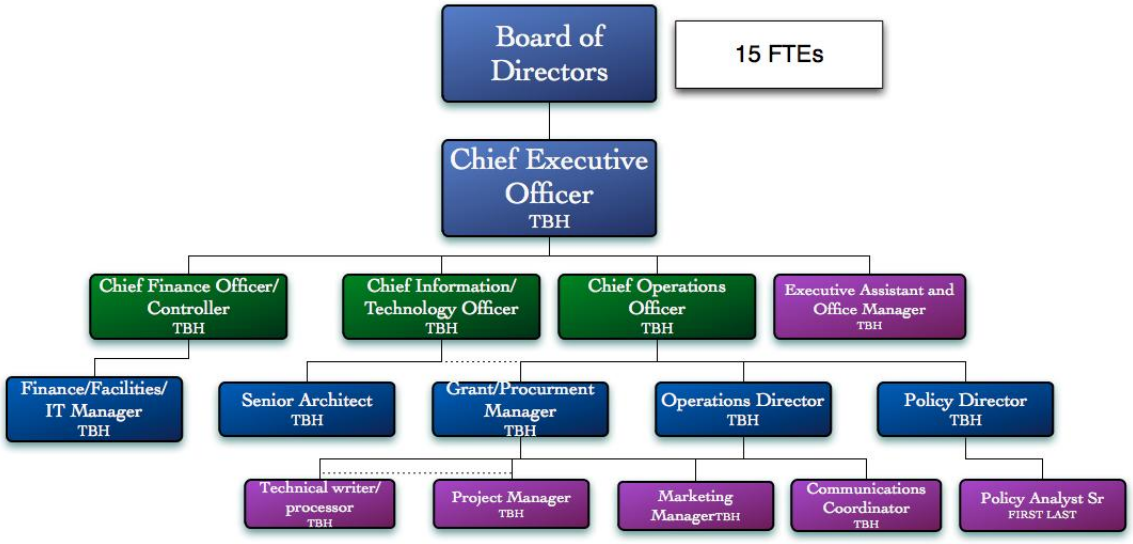
Highlights: Cal eConnect will hire 15 full time employees (FTEs) in the first 6 months of Phase 1 implementation. Organizational policies such as conflict of interest, hiring, procurement and transparency have been drafted and will be finalized in the first 2 months. A business plan will be developed and updated by February 2011, including the strategy for service rollout, marketing and sustainability. A communications and stakeholder engagement plan will be refined and carried out via the eConnect Engagement workgroup with staff support and specific activities will be carried out to coordinate strategy and timeline with other entities supporting the meaningful use of EHRs.

Key Tasks and Timeline from Work plan:

Key Tasks and Deliverables	Target Completion
Build and Staff Cal eConnect Team	November 2010
Developed Cal eConnect Policies and Procedures (conflict of interest, human resources, hiring, etc.)	September 2010
Developed Cal eConnect Business Plan	September 2010
Updated Operational Plan to reflect: • Financial Sustainability Plan • Implementation and evaluation of policies and legal agreements related to HIE • Statewide HIE alignment with other federal programs	January 2011
Developed Communication and Stakeholder Plan: • HITECH Entity Coordination • Stakeholder Engagement Plan	June 2011
Transition Work to Permanent Cal eConnect Team: • Temporary Office Setup (i.e. PBGH) • CaleConnect installed in permanent office • Procurement Process for Supplies • Developed Vendor Strategy and Plan	August/Sept 2010

Staffing

Cal eConnect plans to hire approximately 15 FTEs to drive the work. A draft organizational chart describing these expected positions is provided below. Staff will be hired in a phased manner according to priority and schedule for roll out of services.



The hiring sequence and target hire date is developed based on dependencies identified from the work plan. For example, a CIO/CTO needs to be hired immediately, because

specification/requirements of the Core Services (Entity and Service Registries) need to be finalized by September, so that development can begin and pilot testing can be completed by July 2011. The CEO will be hired first at the end of June 2010 and will be responsible for beginning the hiring process for the other staff members.

Resource Hire Date and Work Stream Dependencies:

Position	Target Hire Date	Work Streams Addressed By Resource
CEO	June	• Build the company • Hire staff • Drive key strategic decisions • Establish critical relationships - reach out to stakeholders, work groups, and other organizations
Technical Consultant (contractor, not FTE)	June	• Begin specifications (requirements) development for Core Services
Executive Assistant	July	• Drive tactical work around building office infrastructure • Assist CEO in day to day work
CTO, COO, Senior Policy Analyst, Project Manager	August	• Strategic and Operational Plan • Developed Grant Management Program and Oversight (i.e. RFP, guidelines, selection, distribution) • Technology Architecture
Procurement/Grant Manager, Communications Coordinator, Technical Writer/Processor	September	• Implement grant making/distribution • Manage communications with state, external entities, media, and stakeholders
Operations Director, Policy Director, Marketing Manager	October	• Develop Policy and Legal Requirements (e.g. Privacy and Security, Patient Consent, Data Use Agreements) • Develop Core Services • Pilot Test Core Services • Drive Promotion and Adoption of Core Services
CFO/Controller	November	• Manage budget • Manage grant financials • Develop and implement sustainability plan
Finance/Facilities/IT Manager, Senior Architect	November	• Develop Core Services • Pilot Test Core Services

Organizational Policies and Procedures

During the planning phase, Cal eConnect drafted the necessary foundational policies and procedures including: Conflict of Interest, Human Resources and Hiring, Data Security, Transparency and Procurement. Immediately after both the Cal eConnect Board of Directors and CalOHII approves the policies and procedures, Cal eConnect will implement them. Each is described briefly below.

Conflict of Interest

Cal eConnect, and its directors and officers are dedicated to serving the interests of Californians in the most honorable and ethical manner possible. One of Cal eConnect's responsibilities is to provide assurance to the public that Cal eConnect's debates, decision-making and governance are conducted solely to accomplish Cal eConnect's purposes and not to benefit other persons or businesses. Among the duties of Cal eConnect's "officials" is to place the best interests of Cal eConnect uppermost when acting on Cal eConnect's behalf. This duty of loyalty, or "fiduciary" duty, encompasses the obligation to avoid or disclose any "other interests" that could dilute, diminish or divide an official's unqualified loyalty and complete commitment to Cal eConnect. Where such interests exist or even appear to exist, they are "conflicts of interest" that Cal eConnect is responsible to identify, manage and assure that they do not interfere with proper governance.

Cal eConnect's policy is to require that all Cal eConnect officials disclose "other Interests". In turn, Cal eConnect's Board of Directors, or delegated representatives of the Board of Directors, is required to review those disclosures and to decide upon the appropriate response to the information disclosed, in accordance with Cal eConnect's procedures for doing so. It is expected that, in most cases, the proper corrective measure will be disclosure of the Other Interests to the Board of Directors. In some cases, however, the official may be asked to "recues" his or herself from debate or resolution of matters in which they have other Interests. In unusual cases, the individual may be asked to resign from their leadership position in Cal eConnect. Conflict of Interest policies and procedures are currently being refined for completion in September 2010.

Human Resources and Hiring

Cal eConnect contracted with a Human Resources (HR) Solutions company, TriNet, to develop hiring policies and procedures, including an employee handbook. These policies cover recruitment and hiring, employee conduct and workplace expectations, performance, compensation and benefits, time off, and employee departure among other policies and procedures required to manage the organization and its staff.

Data Security

Administrative data security policies are included in the Employee Handbook referenced above. Once a Policy Director with privacy and security expertise is hired, they will work with the eConnect Policy Workgroup to develop programmatic data security policies as referenced in the Legal and Policy section. These will be completed by February 2011.

Transparency Policy

The transparency policy, to be finalized in September 2010, clarifies what types of information will be made available to the public, how the information will be made available and what the mechanisms will be to gather public feedback.

Procurement Policy and Procedures

The purpose of Cal eConnect's procurement policy, to be finalized in September 2010, is to establish mandatory and uniform policies and procedures for the procurement of property and services for the organization. Cal eConnect's policy is to adhere to all applicable federal and state procurement laws, regulations, and policies and to conduct procurements in a manner that ensures open and free competition to the maximum extent practicable.

Cal eConnect will perform two procurement and grant /contract cycles – one in the second half of 2010 and one in 2011 – to request proposals, select and obtain services to provide the functions needed to support HIE. If the final Stage 1 meaningful use rule or Stage 2 and 3

rules necessitate new functionality that has not yet been considered, Cal eConnect may need to add subsequent procurement cycles. Each procurement/grant cycle will include the following steps:

- Draft procurement and grant requirements;
- Develop Readiness Assessment Dashboard for Grantees
- Review procurement and grant requirements with appropriate Boards, Committees and stakeholders, and refine requirements based on feedback;
- Draft Request for Proposals (RFPs);
- Finalize and release RFPs;
- Review responses to RFPs;
- Negotiate with top responder(s) and award grant(s) and contract(s); and
- Oversee implementation jointly with the Evaluator (see Evaluation.)

Update Strategic and Operational Plans

As part of the Cooperative Agreement requirements, Cal eConnect must update the HIE Strategic and Operational Plans on a yearly basis. By January 2011, Cal eConnect must have an updated draft of the:

- Financial sustainability plan
- Plan for implementation and evaluation of policies and agreements related to HIE
- Plan for statewide HIE alignment with other federal programs

The following paragraphs and sections identify the steps necessary to complete this deliverable.

Business and Sustainability Plan Development

To complete its sustainability plan, Cal eConnect will assess the market using the market framework, develop a data-driven strategy to offer services that will have the greatest impact and value to stakeholders, identify a marketing plan to gauge the potential customer base and develop a revenue and cost model for potential services. Based on this analysis, the Cal eConnect Board will be able to prioritize those services and target markets that will reap the most value to the organization and lead to sustainability. See the Finance section at end of this Implementation Plan for more information on sustainability.

Assessment

The market data referenced in the strategy section and the appendices represents a high-level survey analysis of the California HIE environment, and some of the prominent gaps in HIE capabilities that will be needed for to enable meaningful use. A more comprehensive and definitive survey will be necessary to establish more precisely how many clinicians and entities will be ready to utilize those Core Services to achieve meaningful use, and how soon that use would be enabled.

In the rural market, the California State Rural Health Association, through RHITC, has already begun this process, and is assembling an information technology baseline assessment. In order to achieve a similar level of granularity for the Urban and Unaffiliated markets, Cal eConnect would require development of an RFP for a comprehensive baseline assessment of capacity in those target markets.

Strategy Development

Based on the data gathered through the assessment phase, the eConnect Business Workgroup and staff will devise priorities in terms of what value-added services to provide and how to phase the implementation and rollout of Cal eConnect services to the various market scenarios. This includes services that Cal eConnect may provide itself or grants and contracts to other entities that will provide the services. The initial strategy will be developed by August 2010 but will be revised as Stage 2 and 3 meaningful use requirements are communicated and as market needs change.

Marketing Plan

Cal eConnect plans to hire a marketing manager as part of its core staff to develop a comprehensive marketing and sales plan by September 2010. The eConnect Engagement and eConnect Business workgroup will contribute to the definition of the marketing plan to ensure the right messages reach the right key stakeholders and customers.

As part of the Business Model development, the eConnect Business workgroup and staff will gather data from key stakeholders within each target market scenario to be able to tailor products and marketing messages to the appropriate customer. Distinct marketing and distribution strategies for the rural scenario, urban scenario and unaffiliated provider scenario will all be included in the marketing and sales plan completed by September 2010.

Through participation in the California eHealth Coordinating Committee Outreach and Education Workgroup, in addition to one-on-one meetings, the Cal eConnect marketing manager will coordinate plans with the RECs, the Medi-Cal EHR Incentive Program, the California Telehealth Network and other partners to enhance effectiveness and cohesiveness of message and to ensure the product reaches the target markets.

Revenue Model

The eConnect Business Workgroup, in coordination with the eConnect Technology Workgroup, will consider alternative products and services Cal eConnect should offer and will develop revenue and cost models to see which alternatives have the greatest potential to sustain Cal eConnect services. By year 3 of the Cooperative Agreement, Cal eConnect should begin to generate revenues that would contribute to the match requirements. The eConnect Business Workgroup will recommend to the Board those strategies which will maximize Cal eConnect's ability to bring in funds. See the Finance section for a discussion on potential revenue options.

Communications and Stakeholder Engagement Plan

During Phase 1 and beyond, Cal eConnect will need to identify key stakeholders and build communications channels and outreach strategies to engage them. Key stakeholders including consumers, physicians, hospitals, regional and local HIOs, safety net providers, health plans and insurers, state, county, and local agencies, professional associations, academic medical centers, and privacy advocates, among others, need to be engaged in a formal manner to support Cal eConnect policies and services.

Communications Plan

Cal eConnect communications staff has drafted a communications plan and stakeholder analysis that will be vetted by the eConnect Engagement Workgroup and other stakeholders. The Communications Coordinator, in partnership with the eConnect Engagement Workgroup will be charged with developing and implementing communications channels and a schedule to perform stakeholder outreach.

During the planning period, Cal eConnect established an initial set of communications tools to enable outreach including:

- Website (completed June 2010)
- E-mail list of stakeholders (completed May 2010)
- Graphic identify (completed May 2010)
- Powerpoint presentations with background information (completed May 2010)
- Initial key messages (completed May 2010)

Between June and September, Cal eConnect will need to increase two-way communication with stakeholders to inform and gather feedback on the Implementation Plan and other future plans using the website and listserve tools.

Currently the following outreach tools are planned in the indicated frequency:

- Board Meetings (monthly)
- Workgroup Meetings (bi-monthly)
- Written Updates (monthly)
- News Releases (as needed)
- Webinars (as needed)
- Targeted audience outreach (as needed)
- Speaking engagements (as occur)
- Website (daily)

Cal eConnect completed a stakeholder outreach schedule for June through December 2010 that includes more detail on the proposed outreach strategies and target audiences. These communication channels will need to be fully formed and functional by April 2011 to allow for adequate education, interaction and engagement with stakeholders on participation with Cal eConnect services and fund allocation programs.

Cal eConnect's communication strategy will also take advantage of the Cal eConnect leadership – the CEO and Board of Directors – as communications vehicles. As detailed in the communications plan, staff will need to educate the Board and work with the CEO to develop consistent messaging and speaking opportunities to inform stakeholders.

Starting in July 2010, or when formed, a representative from Cal eConnect staff or the eConnect Engagement Workgroup will need to participate in the eHealth Coordinating Committee Outreach and Education Workgroup to leverage partners' communication channels and ensure coordination among the RECs, Medi-Cal, and the CTN, among others.

Stakeholder Engagement and Coordination

As detailed in the draft stakeholder analysis, which is currently being updated, Cal eConnect has developed a prioritized list of stakeholders based on their level of influence and importance in Cal eConnect's success. Based on this analysis, priority stakeholders to engage in the first six months include:

- Physician organizations and independent physicians
- Community clinics and rural health
- Local HIOs
- Hospitals
- IDNs
- Ancillary service organizations

- Other related California entities: CalHIPSO, HITEC-LA, Medi-Cal EHR Incentive Program, RHITC

Cal eConnect will use the eConnect Engagement Workgroup, starting in June 2010, to identify key stakeholders within the groups listed above and tailor engagement strategies to those stakeholders. The workgroup will finalize specific engagement strategies, tactics, tools and timeline with staff direction. This will result in a customized communications "campaign" for each of the market scenarios to engage Cal eConnect's priority stakeholders, using the communications tools referenced above.

ARRA/HITECH Entity Engagement and Coordination

Cal eConnect must leverage other California partners invested in supporting the meaningful use of EHRs early in order to reach potential customers in time for the Stage 1 meaningful use deadline and the forthcoming requirements of Stages 2 and 3. There are three primary coordinating mechanisms Cal eConnect will use to achieve this:

1. Multi-stakeholder governance structures including the Board of Directors and Workgroups. The Board was designed to include the Director of Medi-Cal who coordinates the Medi-Cal EHR Incentive Program, the CA Deputy Secretary of Health IT who coordinates HITECH programs across the State, public health representatives, and includes several representatives from the Regional Extension Centers. Workgroup membership will also be purposefully designed to cross-populate with members of the ARRA-funded programs, stakeholders and other partners in the State.
2. Participation in the CA eHealth Coordinating Committee and associated workgroups, whose design is to coordinate activities and leverage lessons learned across all ARRA funded programs in California.
3. One-on-one interaction with staff and leadership from partner organizations.

Specifically, Cal eConnect will need to coordinate and engage with the following key partners involved in supporting the development of health information technology and exchange capacity in California:

HIT Regional Extension Centers (RECs)

Cal eConnect and REC services have a set of critical interdependencies. To meet meaningful use, priority providers must not only use their EHRs but perform a set of tasks that require HIE. Cal eConnect and the RECs must coordinate on needs assessment, vendor selection and purchasing, and the strategic roll out of services to providers in step with REC support of EHR adoption. In addition, communications staff from Cal eConnect and the RECs will work closely to coordinate on the plan for sales and marketing.

CalHIPSO and HITEC-LA are the funded ONC funded HIT Regional Extension Centers (RECs) in California. A third may also form out of the California Rural Indian Health Board (CRIHB) as an inter-state REC. A fourth, CalOptima, which was not ultimately funded through ARRA, may also perform REC activities and should be consulted. The CEO of HITEC-LA sits on the Cal eConnect Board and Cal eConnect plans to nominate a Cal eConnect representative to sit on the CalHIPSO Board. Through this direct connection with RECs, as well as the staff participation on the CHHS' eHealth Coordinating Committee, Cal eConnect will operationalize leadership and technical coordination.

The specific actions that ensure this coordination are:

- Cal eConnect staff participation in monthly eHealth Coordinating Committee meetings and workgroups
- Cal eConnect staff direct coordination with the RECs addressing issues such as: technical interoperability, group purchasing contract provisions to ensure the use of Cal eConnect statewide directories, and interoperability standards compliance
- Cal eConnect Board meetings
- REC staff participation on the eConnect Technology Workgroup and eConnect Engagement Workgroup and/or coordination through the eHealth Coordination Committee Technology and Communications Workgroups

Medi-Cal EHR Incentive Program and Other Relevant State Agencies

Cal eConnect will need to collaborate directly with the Medi-Cal division of CHHS as it completes its Health IT Planning efforts. It is expected that the Medi-Cal Health IT Plan will identify funding needs resulting in requested support to fund Medi-Cal's "fair share" of health information exchange costs. These costs could potentially be directed to Cal eConnect to support Medi-Cal providers in the successful achievement of HIE-enabled meaningful use. Cal eConnect has already taken advantage of some preliminary market assessments performed by Medi-Cal and have discussed coordination to identify pilot communities.

CHHS is also beginning to integrate HIE efforts across its Departments including: Medi-Cal, Public Health (Immunization Registry, Public Health Lab Reporting, clinical preventive services), Social Services (which is in the process of procuring a new Statewide Automated Child Welfare Information System), and Mental Health (working with County Mental Health Agencies to implement electronic medical records for mental health services), among others. Cal eConnect will need to keep up to date on these efforts and become involved where necessary. For example, Cal eConnect will need to coordinate directly with Public Health and the California Immunization Information Registry (CAIR) to strategize around cross-registry data exchange as well as on the California Reportable Disease Information Exchange (CalREDIE) efforts.

The specific actions that ensure this coordination are:

- Cal eConnect Board Meetings
- Cal eConnect staff participation in monthly eHealth Coordinating Committee meetings and workgroups
- Direct collaboration on selecting and executing meaningful use pilot communities through targeted meetings

Workforce Development

The California Health Workforce Alliance and Los Rios Community College District, who received Federal funding for health IT training targeted at community colleges, are also members of the eHealth Coordinating Committee. Cal eConnect intends to support Workforce Development in any way it can, including hosting interns from the certification programs and providing input on the preparedness of those interns to participate in the health IT workforce.

The specific actions that ensure this coordination are:

- Cal eConnect staff participation in monthly eHealth Coordinating Committee meetings
- Cal eConnect staff direct coordination with the CHHS eHealth Workforce Workgroup and the Los Rios Community College awardee addressing issues such as: intern readiness

for workforce, recommendations for training program modifications or enhancements, and providing mentors for programs.
- Cal eConnect staff participation in the CHHS eHealth Workforce Workgroup meetings when possible
- CHWA/Los Rios staff participation on Cal eConnect Business Workgroup as possible.

California Telehealth Network and Rural Partners

The unique aspects of the rural market are characterized earlier in this plan and require close integration with RHITC, which will be vital in determining readiness for each of the communities for the use of Core Services or application for contracts that may be awarded by Cal eConnect.

CalHIPSO is also convening and sub-contracting to a series of Local Extension Centers across the rural counties, which are providing resources to community clinics, public hospitals and individual providers to support EHR adoption.

In addition, Cal eConnect will coordinate with the California Telehealth Network which will deliver inexpensive, dedicated broadband to rural (and other) providers who may use that capacity for training, software as a service and HIE. Until some of the communities have deployed broadband, there will be no need for HIE services and would be considered in a second or third phase of deployment by Cal eConnect.

The specific actions that ensure this coordination are:

- Cal eConnect staff participation in monthly eHealth Coordinating Committee meetings
- Cal eConnect staff participation in targeted meetings with RHITC, CTN and CalHIPSO on rural needs and opportunities.

California Health Information Exchange Organizations

California has several HIOs efforts, including four functioning community-based HIOs that are in production delivering clinical data amongst hospitals, labs, and physicians. This infrastructure represents significant public and private funding invested into advancing the health information technology and exchange body of knowledge. Two of these HIOs are represented on the Cal eConnect Board of Directors and more will be invited as members of the Workgroups. As Cal eConnect's strategy is further developed, a more refined strategy for coordinating with State HIOs will follow.

Coordination with Other States and NHIN Direct

Like its border-states – Arizona, Nevada and Oregon - California faces many barriers to the development of HIE. Recognizing the barrier to interoperability posed by varying state health information privacy laws, efforts will be made to harmonize the disparate requirements of our neighboring states. While California does not have particularly dense populations along its state borders, health care providers, especially large hospital systems and integrated delivery networks (IDNs), have a significant presence in neighboring states and across the country. These institutions are interested in participating in programs that are consistent across state lines, and do not require distinct and inconsistent policy guidance and rules. The State will continue conversations with policymakers, and the public and private institutions from both California and neighboring states.

The emerging NHIN Direct Model may prove to be a valuable resource in addressing both interstate and intrastate HIE, and the State actively seeks opportunities to participate in pilots and demonstrations in these and other efforts to develop interstate compacts to enable cross-border HIE. At the request of CHHS, three California HIOs – Santa Cruz, East Kern County Integrated Technology Association and Long Beach Network for Health – took part in a successful "Coordinating Care across California" NHIN demonstration at the Healthcare Information and Management Systems Society (HIMSS) 2010 Annual Conference and Exhibition. Redwood MedNet also participated in a demonstration using the latest NHIN CONNECT gateway to exchange patient data with Thayer County Health Services in Nebraska. Finally, California's largest IDN, Kaiser Permanente, is now using NHIN CONNECT to link patient records with the US Department of Veterans Affairs and the Department of Defense in San Diego. Additional California HIOs and State agencies expect to participate in demonstrations and pilots using NHIN Connect infrastructure as part of our implementation efforts.

California will continue to track and align where appropriate with national interoperability initiatives. David Lansky, co-chair of Cal eConnect's Board of Directors is a member of the National Health IT Policy Committee and co-chair of the Committee's NHIN workgroup. The Deputy Secretary, Health IT is also a member of that workgroup, and California is a founding member of the NHIN Direct Implementation Work Group. Through these and other interactions, California seeks to advance both the goals of NHIN while building internal infrastructure so that we may take full advantage of the NHIN lessons and move the industry toward ubiquitous, safe and secure movement of health information.

V. Governance

This section describes the mechanisms Cal eConnect will use to convene, coordinate, oversee and manage the implementation of statewide shared services throughout the State.

Highlights: The primary governance body of Cal eConnect will be its 22-member Board of Directors, operating under a set of bylaws in addition to the organizational policies referenced in the Business Operations section. Cal eConnect will also engage a set of volunteer stakeholders starting in June to serve on Workgroups to advise the Board on policy, business, technology and engagement aspects of the plan.

Key Tasks and Timeline:

Task and Deliverables	Target Completion
Board of Directors set	Completed
Board meetings scheduled on calendar	June 2010
Identified required committees and work groups to drive to pilot test of entity and service registries (Technical, Policy, Stakeholder, Business)	June 2010
Developed transition plan to begin new work groups (drive to pilot test)	June 2010
Committee and Work group meetings scheduled on calendar	July 2010

Cal eConnect Board of Directors

Consistent with the requirements of California Senate Bill 337, Cal eConnect has seated a 22 member Board of Directors, including members of the State government, public and private organizations, with a majority of the board comprising non-government employees. The Board has a diverse composition representing a variety of groups and geographies. The current Co-Chairs of the Board are David Lansky, CEO Pacific Business Group on Health (PBGH) and Don Crane, CEO California Association of Physician Groups (CAPG). The seated Board members (open seats will be filled by June 4) include:

Position	Seated	Organization
HIE Organization	Bill Beighe	Santa Cruz HIE
Physician - Independent	Brennan Cassidy, MD	CMA
Health Plan - private	David Joyner	Blue Shield
Co-Chair - at large	David Lansky	PBGH
Co-Chair - at large	Don Crane	CAPG
Health Plan - public	Howard Kahn	LA Care
Consumer	Marge Ginsburg	Center for Healthcare Decisions
Safety net clinic	Ralph Silber	California Primary Care Assoc.

Hospital - public	Ron Jimenez, MD	Santa Clara Valley Health and Hospital System
CEO Cal eConnect	Carladenise Edwards	Cal eConnect
Hospital - private	Tom Priselac	Cedars Sinai
Ca Assembly Committee on Health Chair	TBD	CA Legislature
Ca Senate Committee on Health Chair	TBD	CA Legislature
Ca Secretary of HHS	Jonah Frohlich	California Health & Human Services Agency
Ca State Administrator	Toby Douglas	Department of Health Care Services
Consumer	Mark Savage	Consumers Union
Employer	Ann Stausboll	CalPERS
Health Informatics	Peter Yellowlees	UC Davis
HIE Organization	Laura Landry	Western Health Information Network
Labor	David Regan	SEIU
Physician - Medical Group	Keith Wilson	Talbot Medical Group
Public Health	Ann Lindsay	Humboldt County Public Health

The Board will meet monthly and a meeting schedule has been established. If critical decisions need to be made by the full Board within a timeline that is not consistent with this schedule, ad-hoc meetings may be scheduled. Meetings are open to the public unless information of a confidential nature is discussed.

Cal eConnect has been established as a California nonprofit public benefit corporation. The Bylaws approved by the Board of Directors provide the direction for the conduct of its affairs. All Board members are also required to comply with Cal eConnect's Conflict of Interest policy referenced in the Business Operations section.

Cal eConnect Advisory Workgroups

Cal eConnect shall have workgroups as the Board of Directors may from time to time determine to be appropriate. The primary role of the workgroups is to provide expert advice to the Board and to execute on clearly defined deliverables to support the planning process.

In June 2010, the following workgroups will be initially formed/reconstituted from the operational planning process to support key elements of this Implementation Plan:

(1) eConnect Technology: Vet and provide consensus on plan for technical services, specifications, and standards development and vendor selection.

(2) eConnect Policy: Develop a plan to guide policy development. Build evidence-based policies and procedures necessary to allow providers to take full advantage of Cal

eConnect services. Assist in the development of implementation strategies for privacy and security guidelines developed by CalOHII.

(3) eConnect Engagement: Flesh out specific portions of the communication and engagement plan, especially those relevant to vulnerable and underserved populations.

(4) eConnect Business: Advise on a business model based on the selected set of services, products and target markets. Assist in conducting market analyses to identify further business opportunities for Cal eConnect.

Board Co-Chairs will nominate a Workgroup Chair for each group and the Workgroup Chair will select the Vice-Chair and other members of the group in consultation with the Board Co-Chairs. Members of the workgroups will serve 1-year terms. Initially, workgroups will be composed of more than 3 and up to 10 core members who represent a range of California stakeholders knowledgeable in the respective topics. The groups will consult with additional subject matter experts as needed.

Meetings will be held every other week via phone with a limited set of meetings in person. Small subsets of the workgroup (task group) meetings will be held more frequently as needed. To drive the aggressive schedule, staff will be assigned to draft workgroup deliverables and workgroups will provide feedback.

By July 2010, the following activities must be complete to begin engaging the workgroups:

- Finalize and approve workgroup charters, including schedule of activity that coincides with the work plan
- Identify workgroup leadership and membership
- Assign staff to support workgroups
- Assign kickoff and ongoing meeting schedule

Office of Health Information Integrity Relationship

Cal eConnect expects to work collaboratively with the staff of CalOHII to ensure that all of the requirements and obligations of the grant are met. At a minimum, monthly status meetings will be held to ensure that project expectations are met. In addition, Cal eConnect will submit a bi-weekly status report to CalOHII using the template provided. The report will include the status of each deliverable, expected completion date, budget allocation toward the deliverable and the amount expended to date.

Cal eConnect and CalOHII have agreed on an iterative process for review and approval of required policies and procedures. Under our grant obligations, Cal e Connect will seek OHII's input into procurement decision for any subcontract over $25,000. In general Cal eConnect's implementation and detailed work plans are being reviewed in detail with CalOHII and must be approved prior to Cal eConect moving forward with the execution of the plans.

Audit and Controls and Reconciliation

Cal eConnect staff will work quickly and closely with CalOHII to develop the appropriate processes for monitoring and reporting progress toward meeting agreed upon deliverables. Included in this will be a definition of reporting requirements, timing of reports, change management process and issue triage and escalation.

VI. Legal and Policy

This section identifies the mechanisms Cal eConnect will put in place to provision entities in the core services, implement privacy and security policies, and monitor and enforce such policies.

Highlights: Cal eConnect will coordinate closely with CalOHII/CalPSAB to leverage existing policy frameworks and guidelines. Where policies are not defined, Cal eConnect will use staff expert in the privacy and security of data exchange along with stakeholders in the eConnect Policy workgroup to define and build consensus on policies. For example, Cal eConnect will need to develop requirements that govern the provisioning of entities in the core services. Cal eConnect will develop monitoring and enforcement mechanisms early on to foster and maintain trust in its shared services.

Key Tasks and Timeline:

Key Tasks and Deliverables	Target Completion
Completed legal and policy work for Privacy and Security	February 2011
Completed legal and policy work for Consent	February 2011
Completed legal and policy work for Data Use Agreement	February 2011
Developed Grants Management and Oversight Service	October 2010
Patient Engagement/Vulnerable Populations	TBD

Requirements, Policies, and Guidelines Development Process[6]

Through its legal and policy tasks, Cal eConnect must define its operational policies, align with existing State recommendations on privacy and security measures and determine how to best align with the standards suggested by the NHIN. Relative to its current planned services, Cal eConnect must set up processes to provision entities into the registries, implement data use agreements, monitor the entities' compliance with the agreements and enforce policies where breaches occur. Initial policies will only cover the current scope of Cal eConnect's services and grants but as Cal eConnect expands and offers new services, a flexible process will need to be put in place so that the policies can similarly expand in scope. The following paragraphs identify the current thinking on the Cal eConnect's legal and policy process but it will need to be refined once the eConnect Policy Workgroup is in place.

Privacy and Security Cooperative Agreement Deliverables

The responsibilities of the Legal and Policy deliverables for the Cooperative Agreement are divided between the State through the eHealth Policy Branch of the California Office of Health Information Integrity (CalOHII) and Cal eConnect. As noted in Table 5 at the end of this section, Cal eConnect is responsible for developing operational privacy and security policies by which both participants of the cooperative shared services and recipients of funding under this program will be bound. Cal eConnect will also oversee the implementation of the privacy and security policies in the technical configuration of the HIE architecture and through the subcontracts with regions for services. CalOHII will work closely with Cal eConnect to develop

[6] Note: Much of this content was adapted from the New York eHealth Collaborative.

use cases that align with the overall strategy of HIE in California. The CalOHII's eHealth Policy Branch will test each use case with an end result of clear policies that Cal eConnect can implement as HIE services are established.

Collaboration with the CA Privacy and Security Advisory Board

CalOHII established the California Privacy and Security Advisory Board (CalPSAB) as a public-private advisory body to provide the Secretary of Health and Human Services with policy recommendations for California. The division of responsibility for the Cooperative Agreement requirements related to legal and policy work are listed in Table 5 below.

Cal eConnect plans to transition several of the members of CalPSAB's HIE Committee to the eConnect Policy Workgroup to continue their efforts in defining successful HIE policy and reduce gaps in translation. The first charge of the eConnect Policy Workgroup will be to identify the exact policy deliverables that are needed beyond those detailed in the Cooperative Agreement and how CalPSAB can be leveraged in defining and piloting those policies.

Policy and Guideline Development Process

In general, the eConnect Policy Workgroup will develop recommendations and present them to the Board for adoption. This workgroup will seek input from other eConnect workgroups and California stakeholders in order to inform the strategy and ensure the trust of the community in the final product, according to the Stakeholder Engagement Plan. Cal eConnect will also hire a Policy Director with HIE privacy and security expertise, as described in the staffing model, to drive the workgroup's deliverables and coordinate with other policy-making bodies. Finally, the policies will require review from legal counsel to ensure they comply with local, State and Federal rules and regulations.

Cal eConnect intends to create a statewide governance process that collaboratively develops Statewide Policy Guidance including common policies and procedures, standards, technical approaches and services for California's health information infrastructure. Cal eConnect's key responsibilities include (1) convening, educating and engaging key constituencies, including health care and health IT leaders across the state, HIOs, Community Health Information Technology Adoption Collaboratives (CHITAs), and other health IT initiatives; (2) developing Statewide Policy Guidance through a transparent governance process, and (3) evaluating and establishing accountability measures for California's health IT strategy.

The Statewide Collaborative Process (SCP) described below is intended to provide a framework where developing policies and standards for California's health information infrastructure go hand-in-hand with field testing them as part of meaningful use implementation. This framework allows for the validation and ongoing refinement of policies and standards to ensure health information liquidity and value realization from California's health information infrastructure. This is a crucial process over the next few years.

Cal eConnect recognizes there is a body of HIE policy work created by California and other states, e.g. New York eHealth Collaborative, and organizations, such as the eHealth Initiative that it can leverage. Cal eConnect will use these organizations' work to guide the development of our own requirements, policies, and guidelines. The eConnect Policy Workgroup will review the work done by the New York eHealth Collaborative related to the Healthcare Efficiency and Affordability for New Yorkers Capital Grant Program (HEAL) and other similar efforts to determine its relevance to California's HIE landscape, and to accelerate the California process by following a model that has already been established in a large, complex state with similar policy and healthcare delivery challenges.

As part of its initial charge (July – September 2010) the eConnect Policy workgroup will:

1) Refine the current process and timeline for development and implementation of policy guidelines and will clarify the role of the State and Cal eConnect in defining and implementing policies

2) Review other states' policy frameworks, specifically those that have similar regulatory and healthcare delivery environments
    a. Recommend for adoption all elements that make sense to replicate
    b. Adapt use cases to be California-specific

3) Socialize and gain buy-in for the California policy and requirements framework. The eConnect Policy workgroup will build on CalPSAB's work to finalize and adopt operational Security Policies and Procedures for HIOs and their participants in California that are compliant with state and federal law. These will cover guidelines on who should comply with the policies and procedures as well as lay out the policies on consent, authorization, authentication, access, audits and breaches. They will also provide model documents for consent and disclosure, among others.

4) Provide input to the development of RFP specifications for the core services. This includes recommending policies on provisioning, monitoring and enforcement of entities participating in the core services. It also includes the development of a data use agreement among participating parties, which would need to conform to guidance from CalPSAB and the NHIN.

5) For services that Cal eConnect directly operates, the eConnect Policy workgroup will work with the eConnect Technology Workgroup and technical staff to develop policies and procedures that should govern the privacy and security of architecture and transactions using the core services.

Continuous Improvement

Once initial policies are defined they will need to be tested and evaluated through pilots. Cal eConnect is currently working to define the criteria for pilot communities and opportunities to collaborate on a pilot with CalOHII, Medi-Cal, RHITC, CTN and other partners.

Section 3013(h) of the HITECH Act, requires the Secretary to complete an annual evaluation of the activities conducted under this program and, in awarding cooperative agreements under section 3013, implement lessons learned from the evaluations. This will shape future program guidance and enable continuous improvements to the program. Additionally, ONC will collaborate with the states and provide technical assistance in order to ensure that lessons learned are implemented in a way that promotes quality and efficiency improvement through secure and appropriate electronic exchange of health information. Cal eConnect will provide an evaluation and oversight manager who will be responsible for the monthly and quarterly reporting for all business and technical operations activities.

Oversight and Evaluation

Cal eConnect needs to put in place mechanisms for appropriate oversight of HIE for the contracts to regions and users of the Core Services. This includes hiring the Policy Director to oversee policies and procedures for both the technology core services implementation, data use agreement and implementation of the contracts with regional stakeholders. Cal eConnect will

require strong financial management in the form of grant management, federal funding accounting, oversight and management.

Grants Management and Oversight

Cal eConnect plans to reserve a portion of the 18-month budget for allocation to regions to pilot Cal eConnect services and policies, expand HIE capacity where it already exists and provide seed funding to start up HIE initiatives to further enable meaningful use. Cal eConnect must support the thorough and vigilant management and oversight of these grants and contracts to regions to ensure that dollars are spent responsibly and have the intended impact.

Each of the examples below provide Cal eConnect with areas to be considered for contracts:

- Regions without HIE- Both Urban and Rural Markets have a small, limited number of HIEs, some planning at a community level and or IDN level has taken place. These start up organizations would benefit from early funding to advance their HIE development activities and to help build the necessary technology for them to eventually require the need for Cal eConnect Core Services.
- Expanding regional HIEs- This strategy would enable the most rapid advancement of MU to the broadest markets. In addition, by providing funding for the development of the local HIE capabilities as a quid pro quo for the purchase and use of Core Services, the strategy would seed the market for Core Service use in the most rapid manner.
- Piloting new capabilities – While there is some level of sophistication in the HIE market in CA, there are many policies, technologies and services that need further development to achieve Stage 1 and especially Stage 2 and 3 meaningful use requirements.

There are key decisions that Cal eConnect still needs to make regarding funding allocation strategy. For example, Cal eConnect can select a particular meaningful use measure and target implementation of that measure in every community and support only that effort in the communities. Alternatively, Cal eConnect can provide contracts to the communities that are closest to providing scalable resources to achieving all measures of meaningful use and bring the community to the “last mile” for achieving meaningful use by 2011. Finally, Cal eConnect could utilize contracts with the communities to support planning and readiness to ensure that “no provider is left behind” in their process towards achieving meaningful use.

During the planning period, Cal eConnect staff will consolidate the information necessary to assist the Board in making decisions about the strategy for allocating financial resources and business operation support to the communities. Starting July 2010 the Board may decide to engage a separate workgroup on developing the requirements for resource allocation.

Once the Procurement/Grants Manager is hired in September 2010, they will take inputs from the interim staff and Workgroup to develop the full guidelines for the grant program including developing program objectives, criteria for grantee selection, defining the assessment, evaluation and award procedures, and the monitoring and enforcement process. This will be submitted to the Board for approval. Staff will ensure that the proposed program guidelines conform to the existing Cal eConnect policies referenced above.

These program management guidelines need to be developed by October 2010 so that the process for distributing grants, including RFP, evaluation and award, can be put in place.

Table 5: Privacy and Security Requirements for Cal eConnect:

Privacy and Security Requirements Under the Cooperative Agreement	Strategy/Mechanism	Outcomes	Responsible Party	Timeline
Harmonize laws: Identify and harmonize the federal and state legal and policy requirements that enable appropriate health information exchange services that will be developed in the first two years.	• Outline current CA laws, trust agreements and regulations that are in place or have been proposed that serve to advance appropriate HIE in California • Outline current laws, trust agreements and regulations that are outdated, overlapping, and/or impede appropriate HIE in California and identify changes expected or needed • Use the existing CHILI tool to help align and harmonize laws • Harmonization of state law with federal legal and regulatory requirements, including, HIPAA and ARRA and the data use agreement	• Publish Identified Rules (CHILI) • Promulgate Regulations • Updated HIE Privacy and Security Guidelines • Published Data Use Agreements • Recommend ation Legislative Proposal	• The EHealth Policy Branch of Health and Human Services under the direction of the California Office of Health Information Integrity will retain responsibility for this deliverable.	• June 2010 – December 2014
Policy Framework: Establish a statewide policy framework that allows incremental development of HIE policies over time, enables appropriate,	• Review and confirm the privacy and security principles set forth by the CalPSAB • Develop framework for consolidated privacy and	• California HIE Privacy and Security Policy Framework • Initial HIE	• The EHealth Policy Branch of Health and Human Services under the direction of the California Office of Health Information Integrity will retain	• Completed

Privacy and Security Requirements Under the Cooperative Agreement	Strategy/Mechanism	Outcomes	Responsible Party	Timeline
inter-organizational health information exchange, and meets other important state policy requirements such as those related to public health and vulnerable populations.	security state laws • Articulate guidelines on consumer privacy, including consent policy and methodologies where applicable, data use parameters, access controls, etc.	Privacy and Security Guidelines	responsibility for this deliverable. • This has been completed and vetted through CalPSAB.	
Enforcement Mechanisms: Implement mechanisms that ensure those implementing and maintaining health information exchange services have appropriate safeguards in place and adhere to legal and policy requirements that protect health information, thus engendering trust among HIE participants	• Develop recommendations regarding the enforcement of privacy and security regulations, agreements and policies across HIE initiatives in California that are contracted with Cal eConnect.	• Enforcement mechanisms , e.g., • Licensing sanctions • Data Use Agreement Revocations • Monetary Penalties	• Cal e Connect will utilize the policy work group and the Privacy and Security Officer to determine and implement mechanisms for enforcement of contracts and technical services agreements. • Quarterly progress reports will be provided to the E Health Branch to inform and recommend issues related to enforcement under current guidelines.	• December 2010 – December 2013
Data Sharing Agreements: Minimize obstacles in data sharing agreements, through, for example, developing accommodations to share risk and liability of HIE	• Model inter-organizational data sharing agreements • Conduct a detailed use case analysis for determining the efficacy of proposed legal and policy recommendations	• Published Data Sharing Document • Community Pilots to test Data sharing	• Cal e Connect will utilize the policy work group, staff legal council and the Privacy and Security Officer to modify the existing NHIN DURSA with a	• Begin July2010 • Completed data use/services

Privacy and Security Requirements Under the Cooperative Agreement	Strategy/Mechanism	Outcomes	Responsible Party	Timeline
operations fairly among all trading partners.	with respect to operating an HIE in California	agreements	California Amendment for technical services. • Cal eConnect will also provide a data use agreement model for the HIE's with which it will contract for services. • Quarterly progress reports will be provided to the E Health Branch to inform and recommend issues related to the data use agreement.	agreement by September 2010 for contractors and vendors.
Annual Evaluation: Ensure policies and legal agreements needed to guide technical services prioritized by Cal eConnect are implemented and evaluated as a part of annual program evaluation.	• Develop criteria and responsibilities regarding the annual evaluation of policies and agreements put in place by the Cal eConnect.	• Develop an Evaluation Process and/or Tool Kit to evaluate the contract and technical services agreements and programs	• Cal e Connect will utilize the policy work group, staff legal council and the Privacy and Security Officer to modify the existing NHIN DURSA with a California Amendment for technical services. • An annual report will be provided to the E Health Branch to inform and recommend issues related to the political and legal agreements established for technical services.	• Begin January 2011

VII. Finance

This section describes the initial 18 month budget and the process for developing future costs and sustainability models in the coming years.

Highlights: The phase 1 budget includes plans to distribute $14.8 million in funds with about one third to cover administrative costs, one third for developing the core services and one third to be distributed as grants and/or contracts. A sustainability plan will completed by Febuary 2011.

Key Tasks and Deliverables	Target Completion
Finalize Budget (1-2 years)	Completed
Finalize Budget (3-4 years)	June 2011
Developed alternative revenue generation	July 2010
Developed Sustainability Plan, approved and implementation begins	February 2011 – June 2011
Put in place interim financial support (Charlie Quaid)	July 2010
Coordinate with the state on documentation requirements for financial transactions	July 2010
Developed processes for CHHS Grant Management	TBD

Finalize Phase 1 Budget

Cal eConnect has used interim financial support from PBGH to develop a budget for the first 18 months of implementation, or "Phase 1". Once a permanent CFO is hired, they will take over oversight of the Phase 1 budget and future budget development activities.

Cal eConnect's Implementation Phase 1 budget of $14,800,000 covers 18 months from July 1, 2010 through December 31, 2011. During this phase, Cal eConnect will focus on developing and driving adoption for the Core Services (Entity and Service Registries) and associated policies as defined in the Implementation Plan.

The budget is estimated based on the following assumptions highlighted in this plan:

- **Cal eConnect staffing:** During the first 6 months of this phase, Cal eConnect will hire up to 15 full time staff in order to support the development of Core Services, policies and organizational structure.
- **Pacific Business Group on Health (PBGH) shared resources:** During the first 6 months of this phase PBGH Shared Resources will transition to Cal eConnect staff as they are hired. It is anticipated that Cal eConnect will move to its own facility in the July/August timeframe and no longer require the use of PBGH facility at that time.
- **Core Services:** Cal eConnect will complete, test and deploy core services including Entity and Service Registries and implement the associated policies.
- **Grantmaking:** Additional funds will be used to support regional activities focused on enabling meaningful use through health information exchange.'

As demonstrated in Table 6 below, Cal eConnect plans to distribute funds with about one third for Cal eConnect administrative costs, one third for developing the core services and one third to be distributed as grants and/or contracts to:

- Create HIE capacity in regions where it is limited or lacking

- Expand size and scope of existing regional HIEs
- Pilot new capabilities (e.g. consent management)

Table 6: Estimated Phase One Budget Summary (July 10 – Dec 11)	
Category	Total Funds Requested
Personnel	$3,061,800
Travel	$97,800
Facilities	$280,250
Furniture	$104,650
Equipment	$118,315
Supplies	$113,900
Contractual	$997,295
Communications	$174,760
Core Services Development	$5,000,000
Other	$126,427
Grantmaking	$4,724,803
TOTAL	$14,800,000

Sustainability Plan and Year 3-4 Budget

As described in the Business Operations section, once the strategy for service and policy solutions is finalized, the eConnect Business Workgroup will develop cost and revenue estimates for the services that Cal eConnect plans to deliver or oversee in the next phases of the grant agreement. The updated sustainability plan must be submitted to the Federal Government for approval by February 2011.

Similarly, the eConnect Business Workgroup with the CFO will develop cost and revenue estimates for the services that Cal eConnect plans to deliver or oversee in the next phases of the grant agreement to complete the Year 3-4 budget.

Potential Sustainability Revenue Models

The proposed Sustainability Plan will answer critical questions for generating revenue such as: 1) Who will have to pay for services; 2) What type of services can generate fees; 3) What type of revenue model will be most appropriate in each stage of Cal eConnect's development; 4) How much can be charged for each type of service?

In order to develop a revenue model, the Strategic Framework/Plan, including market sizing, target market, marketing, and distribution strategies must be completed. These strategies will inform the Business Workgroup on which revenue model will most likely to gain traction and give indications on when the revenue model may need to evolve into another model. There are four major revenue models that are currently utilized by various HIE's:

- Transaction Fee Based
- Membership Dues
- Subscription Fees (per services)
- Grants and Other Supplemental Income

In assessing the most appropriate revenue model for long term sustainability, three major factors must be considered. Because each customer base (Payers, Physicians, Hospitals, etc.) will have its own distinct needs and services that it is willing to pay for, revenue models must be developed to fit the needs of the customer. This interaction between Customer Needs, Services Offered (by Cal eConnect) and potential Revenue Model will be part of the work done by the Financial Workgroup in July and August of 2010.

Factors to Consider for Future Sustainability:

Customer Needs	Services Offered	Revenue Model
Health Plans (payers) Physicians Hospitals Others	Core Services Value Added Services Other Services	Transaction Fee Based Membership Dues Subscription Fees Grants & Supplemental Income

Transaction Fee Based

Description: As the name implies, a Transaction Fee Based model simply charges a set rate for each transaction that occurs through the services that Cal eConnect provides. Same or different rates can be set for the Core Services and the Value Added Services. This type of model assumes that all services provided are essential and provide a high inherent value, such that customers would be willing to pay for each usage.

Potential Usage: This model is more appropriate in the beginning stages of developing services. Transaction fees can be quickly set up and put in place. However, as a long term sustainability model, it may be more difficult to grow services and adoption of services using this model.

Pros	***Cons***
• Relatively easy to set up and understand • Low risk investment for customers, as they can opt-in or opt-out easily • ROI and break even for Cal eConnect and for customers are easy to calculate and transparent • Good starting model	• Can incent adverse behavior - if entities need to cut costs, they may choose not to use the service when they should • Costs to customers can balloon as the fees are variable costs • Hinders growth of new Cal eConnect services - Mature HIE's are noticing that Providers/Hospitals are reluctant to pay for new services as it represents a new set of transaction costs

Membership Dues

Description: Under this model, flat fees are charged on a monthly or yearly basis for the entire basket of services that Cal eConnect provides. This model has the advantage in that it is easy for customers to understand the pricing structure. However, it raises a fundamental issue around how additional services would be paid for and scalability of future revenue stream.

Potential Usage: Membership Dues model, similar to Transaction Fees Based, is easy to start with and may initially be easier to drive adoption amongst customers using this fee structure. However, it also runs into similar problems in that it may be harder to grow and fund future Cal eConnect services and harder to scale revenue.

Pros	***Cons***
• Transparent and easy to understand pricing • Predictable revenue stream • Easy for Cal eConnect to implement initially, covering the two main Core services and potential 1 or 2 other Value Added services	• Issues with growth – how will additional services be paid for, both during development as well as operationally • Pricing is tricky as some customers may not want/need entire basket of services • Hospitals may assume, as members, that they have voting rights

Subscription Fees (per service)

Description: A Subscription Fee based model combines features from both the Transaction Fee Based and the Membership Dues models. It is similar to the Membership Dues model in that it charges a flat monthly or yearly fee. However, instead of a blanket rate across an entire basket of services, customers can choose, *a la carte*, which services they really need. Each service is tied to a rate and the customer is charged based on the basket of services that is selected. Note that while rates are charged for services, this is a flat rate and not a fee charged at each transaction. This model attempts to capture the ease of using membership based fees while allowing the company to grow services in the future.

Potential Usage: A customer centric approach that resolves some of the drawbacks in the other models, Subscription Fees model is both scalable and promotes growth of future services. However, it takes time to develop this model and it is a model that becomes more useful as Cal eConnect matures and develops a bigger basket of services.

Pros	***Cons***
• Pricing is transparent and easy to understand • Predictable revenue stream • Better opportunity for enhancing services • More potential for growth • More customer focused – good for addressing diverse needs of customers	• Harder to begin with this model, as there may not be enough services at the outset to warrant a menu based approach • Takes a longer time for the model to mature

Grants and Other Supplemental Income

Description: This category of revenue model covers other forms of revenue generation, such as applying for Grants and Capital Fund Raising campaigns. While these sources of revenue can be significant and can be repeated at regular intervals, they should be viewed as one-time

sources of capital because they are not tied to revenues generated from Cal eConnect services (not operating income). They can be very useful when selectively used to fund specific projects or growth initiatives.

Potential Usage: These sources of income should be treated as strategic assets and as a supplement to other revenue models in a Sustainability Plan. Actual long term revenue stream should be tied to operation activities, and the use of grants should be targeted towards one-time development projects.

Pros	***Cons***
• Funds can be material	• Should not be the central part of a sustainability plan

VIII. Risk Mitigation

Cal eConnect will need to develop a full risk assessment and mitigation strategy, which would fall under the direction of the Chief Operations Office. The mitigation plan will be developed as part of ongoing work approved by the Board and in collaboration with CalOHII.

Table 7 details a subset of the risks that Cal eConnect's mitigation plan will need to address separated into two categories:

- Financial -- This is the traditional financial risk related to the value of the services delivered by the organization as it is perceived by the purchasers of the service
- Business
    - Operating -- How the company is structured, and the details of its basic logistics in order for it to carry out its plan successfully
    - Market -- To what extent the market for the HIE services is ready for its adoption, what barriers or obstacles if any exist, and how well the marketing plan meets market needs and obstacles
    - Execution -- Ability of the Cal eConnect team to execute on all of the tasks given their complexity and dependencies on other organizations' strategy and policies.

Table 7: Risks and Mitigation Strategies			
Risks	Level	Potential Impact	How Risk Will be Addressed
Financial			
Lack of funding in the event that the Cooperative Agreement dollars to be distributed to Cal eConnect from the State are held longer than anticipated in State appropriations due to overall budget approval delay	Medium	a) May affect ability to execute strategy on schedules listed in this implementation plan b) May delay services being delivered to market	The plan to address this risk is: 1. Pursue interim financial support from philanthropic organizations in the State whose missions are to improve healthcare delivery. 2. Engage volunteer workgroups to execute on critical tasks with staff support. 3. Pursue contracts for future services from organizations that find value in the offered services 4. Services contracts will dictate that successful contractors go "at risk" for the development
Most stakeholders in the State have not yet committed to provide matching funds or ongoing sustaining funds to Cal eConnect.	High	May affect ability to provide matching funds for 2011 and beyond, and may affect ongoing funding for sustainability	The plan to address this risk has five aspects: 1. Hire an expert in sales and marketing to communicate the value of Cal eConnect services to key stakeholders 2. Begin to approach potential funders to get letters of commitment for purchasing Cal eConnect services and contributing to future funding 3. Start up the eConnect Business Workgroup to devise ongoing business opportunities and creative funding sources for sustainability 4. Study other states' sustainability approaches. Cal eConnect has already spoken with an expert on HIE business models to gather some of this information. 5. Perform ongoing assessments of the most effective revenue models based on the body of users
Business – Operating			

Cal eConnect is a new business with a new management team and board of directors	Medium	Possible delay in ability to execute strategy	This risk is mitigated by: 1. An experienced CEO who has experience with startups and health IT content knowledge 2. A board of directors whose members are committing significant in-kind resources to support the rapid build out of operations 3. An experienced fiscal sponsor, Pacific Business Group on Health, providing financial and operational expertise 4. Consultants with in-depth subject matter expertise
Business – Market			
Privacy/security concerns may delay signing of data use agreements.	High	Possible delay in use of core and value-added services.	The plan to mitigate this risk has several aspects: 1. Work in close collaboration with CalOHII through the eConnect Policy Workgroup to adopt lessons learned in privacy and security of information exchange 2. Hire a Policy Director with expertise in privacy and security who can drive consensus on contentious issues 3. Perform pilots to test the implementation of privacy and security guidelines in existing exchange communities to learn what does and does not work 4. Actively participate in the development of the Data Use and Reciprocal Support Agreement (DURSA) for the NHIN and work with stakeholders to adapt a data use agreement or "rules of the road" for California as soon as possible 5. Continue engaging individual organizations through our stakeholder engagement plan to resolve specific concerns
Business reasons preventing data providers from taking advantage of Cal eConnect services. These reasons include: 1. Perceived concern about "competitors" having access to their data	Medium	May delay Cal eConnect's ability to accelerate expansion of HIE, and may affect value of HIE to clinician	These issues are mitigated by the following factors: 1. Healthcare provider organizations will develop business strategies to address this due to the meaningful use requirements 2. The short window for maximizing meaningful use incentives will cause organizations to reprioritize their goals 3. Cal eConnect will work with HIT&E (EMR, HIE, etc.) vendors and NHIN Direct to ensure technical requirements for use are compatible

2. Other high-priority HIT projects within their organizations that are more urgent 3. The cost of meeting requirements to participate in the service registry, for example, is too high		users.	with required EHR certification 4. Cal eConnect will work with public hospitals and safety net organizations to raise resources to retrofit systems as necessary 5. Convene a subgroup of the eConnect Technology workgroup to ensure CIOs and CTOs have support in negotiating with vendors to ensure ability to comply as core to products
Legal reasons preventing healthcare providers from signing data use agreements	Medium	May delay Cal eConnect's ability to accelerate expansion of the HIE, and may affect value of HIE to clinician users.	Mitigation steps are: 1. Convene a sub-group from the eConnect Policy workgroup to use existing Data Participation Agreements in the State to develop a data participation agreement that is compliant with all federal, state, and local regulations 2. Convene public discussions where compliance officers and legal counsel can ask questions and provide input
Business – Execution			
Services may be too late to market to meet meaningful use deadlines	High	May result in lack of sustainability for infrastructure	Cal eConnect will need to engage and coordinate with partners early such as RECs, existing HIOs and IDNs to provide some HIE services infrastructure and expand size and scope of offerings. Cal eConnect's Business Workgroup will need to explore the potential to officially endorse existing organizations as being able to meet certain meaningful use requirements dependent on HIE.
May be too far ahead of standards	Medium	May not be supported as an approved activity by ONC due to lack of defined standards	California is participating as a partner in the NHIN Direct project, and has stated its intention to be a pilot and share lessons learned in order to add to the body of knowledge. It is likely that California will drive the development of the final standards. California is working closely with the NHIN Direct leadership.
Selected vendor(s) may not deliver on schedule	Medium	May result in delays to	Cal eConnect will use will use the Project Management Methodology (PMM), which is based on the Project Management Institutes' Project

		market	Management Body of Knowledge (PMBOK). 1) Cal eConnect will continue to utilize its stable, proven methodology for our approach to the project delivery. The methodology aligns with current industry standards for project management. The chosen project methodology approach consists of the following sequential activities: (1) Initiate, (2) Plan, (3) Execute, (4) Delivery, and (5) Close. 2) In addition, Cal eConnect will use a Value Management (VM) methodology. The VM methodology is a derivative of the Earned Value Management System required for multi-million dollar federal performance contracts. The team will plan, budget, and schedule all work in time-phased "planned value" increments, constituting a cost and schedule "performance measurement baseline." VM then provides an objective, quantifiable measurement of work performance, reported as cost and schedule variances from this baseline. In this way, VM provides an early indication of project cost and schedule performance deviations and can provide early insight into issues that might not otherwise be detected until later in the project when they are more costly to correct. By focusing upon these variances, we can prioritize survey activities to quickly and efficiently mitigate them. 3) Cal eConnect will create, at a minimum, following PM and VM documents: a) Work Breakdown Structure (WBS) in accord with the Statement of Work (SOW) b) Organizational Breakdown Structure (OBS) c) Responsibility Assignment Matrix (RAM) d) Contract Performance Reports (CPR)